UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LAW ENFORCEMENT HEALTH BENEFITS INC., on behalf of itself and all those similarly situated, *Plaintiff,* v. ASTRAZENECA PHARMACEUTICALS L.P.; ASTRAZENECA L.P.; ASTRAZENECA UK LIMITED; HANDA PHARMACEUTICALS, LLC; PAR PHARMACEUTICAL, INC., and ACCORD PHARMACEUTICALS, INC. *Defendants.*	Case No. **19-cv-8296** **CLASS ACTION COMPLAINT AND JURY TRIAL DEMAND**

Plaintiff Law Enforcement Health Benefits ("LEHB" or "Plaintiff"), on behalf of itself and all others similarly situated, brings this End-Payor Class Action Complaint against AstraZeneca Pharmaceuticals L.P.; AstraZeneca L.P.; AstraZeneca UK Limited (collectively, "AstraZeneca"); Handa Pharmaceuticals, LLC ("Handa"); Par Pharmaceutical, Inc. ("Par"); and Accord Pharmaceuticals, Inc. ("Accord") (collectively, AstraZeneca, Handa, Par, and Accord are referred to as "Defendants"), for Defendants' violations of the state antitrust and consumer protection laws concerning the pharmaceutical drug Seroquel XR (quetiapine fumarate extended-release tablets) ("Seroquel XR"). Based on (a) personal knowledge, (b) the investigations of counsel, and (c) information and belief, Plaintiff alleges:

I. INTRODUCTION

1. The U.S. sales for branded Seroquel XR exceeded $1 billion annually for AstraZeneca prior to the introduction of generic competition. Handa/Par and Accord recognized the huge market potential for competing generic versions of Seroquel XR and each filed an abbreviated new drug application with the FDA seeking approval to market different

strengths of generic Seroquel XR. In response to the threat of generic competition, AstraZeneca filed separate patent litigation against Handa/Par and Accord alleging that their purported generic versions of Seroquel XR infringed upon AstraZeneca's patents over the drug. Rather than risk losing the patent litigations and allowing generic versions of Seroquel XR to reach the market, AstraZeneca induced Handa/Par and Accord to each settle their respective patent litigation by entering into anticompetitive agreements whereby (1) Handa/Par[1] and Accord agreed not to compete in the market for Seroquel XR from approximately September 29, 2011 until November 1, 2016, thereby allocating the entire Seroquel XR market to AstraZeneca during this roughly 5 year period; (2) AstraZeneca agreed not to compete in the generic Seroquel XR market from roughly November 1, 2016 until May 1, 2017 thereby allocating the entire market for generic versions of Seroquel XR to Handa/Par and Accord for this six month period; and (3) AstraZeneca made a large unjustified reverse payment-- *i.e.*, payments from the patent holder, AstraZeneca, to the alleged infringers, Handa/Par and Accord, and Defendants had no procompetitive justification or other legitimate explanation for the payments.

2. As described in more detail below, Defendants violated state antitrust and consumer protection laws, by entering into the anticompetitive agreements that allocated markets, restricted output, and improperly maintained AstraZeneca's market and monopoly power by (1) delaying competition from lower-priced generic Seroquel XR that would have entered the market earlier; (2) delaying competition from authorized generic Seroquel XR that would have entered the market earlier; and (3) fixing, raising, and maintaining the prices of Seroquel XR and its generic equivalents at *supra*-competitive levels.

[1] As set forth below, Handa subsequently assigned these unlawful agreements to Par, which performed the agreements, sold generic Seroquel XR at *supra*-competitive prices, and shared the illicit gains with Handa.

II. NATURE OF THE ACTION

3. LEHB seeks to represent itself and a class of similarly situated end-payors to recover overcharge damages arising from AstraZeneca's anticompetitive agreements with Handa/Par and Accord that delayed generic competition for Seroquel XR, a prescription drug approved to treat depression, bipolar disorder, schizophrenia, and other illnesses.

4. Prior to the market entry of generic versions of Seroquel XR, AstraZeneca's U.S. sales of branded Seroquel XR exceeded $1 billion annually.

5. Generic manufacturers Handa and Accord recognized the huge market potential for generic versions of Seroquel XR and, between June and December of 2008, each became the first generic drug maker to file an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to market certain strengths of generic extended-release quetiapine fumarate tablets. Handa was the first to submit an ANDA (No. 90-482) for the 50mg, 150mg, 200mg and 300mg strengths of extended-release quetiapine fumarate tablets, with Seroquel XR as its Reference Listed Drug.[2] On June 18, 2008, Accord became the first generic drug maker to file an ANDA (No. 90-681) for the 400mg strength of extended-release quetiapine fumarate tablets, with Seroquel XR as the Reference Listed Drug.[3] Handa filed an ANDA for the 400mg strength thereafter.[4]

4. Pursuant to 21 U.S.C. § 355(j)(2)(B), Handa sent AstraZeneca four separate Paragraph IV notice letters dated July 10, 2008, July 23, 2008, October 16, 2008, and

[2] *See* ANDA Approval Letter from Carol Holquist, Deputy Director, Office of Regulatory Operations, FDA, to Meredith Selby, Senior Director, Regulatory Affairs, Par Pharmaceutical Inc., at 2 (May 9, 2017), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/090482Orig1s000ltr.pdf

[3] *Id*. *See also* Final Approval Letter from Carol Holquist, Deputy Director, Office of Regulatory Operations, FDA, to Sabita Nair, Senior Director, Regulatory Affairs, Accord Healthcare Inc., at 2 (Nov. 1, 2016),

[4] Paragraph IV Patent Certifications, August 27, 2019, https://www.fda.gov/media/82686/download

November 14, 2008.[5] Accord sent AstraZeneca two separate Paragraph IV notice letters dated September 5, 2008 and January 23, 2009.[6] In the Paragraph IV notice letters, Handa and Accord each certified that they would seek final FDA approval to market, and intended to launch, their generic Seroquel XR products prior to the expiration of the follow-on patent purportedly covering Seroquel XR, U.S. Patent No. 5,948,437 (the "'437 Patent"), which Handa and Accord claimed was invalid and/or would not be infringed by Handa's and Accord's respective proposed generic Seroquel XR products.

5. The '437 Patent expired on May 28, 2017. The regulatory exclusivities associated with the '437 Patent expired on November 28, 2017.

6. On July 28, 2008, AstraZeneca filed a complaint against Handa in the United States District Court for the District of New Jersey, alleging that Handa's filing of its ANDA No. 90-482 relating to its 200mg, 300mg and 400mg strengths of generic Seroquel XR infringed the '437 Patent under 35 U.S.C. § 271(e)(2)(A).[7]

7. On October 28, 2008, AstraZeneca filed a complaint against Handa in the United States District Court for the District of New Jersey, alleging that Handa's filing of its ANDA No. 90-482 relating to its 50mg strength of generic Seroquel XR infringed the '437 Patent under 35 U.S.C. § 271(e)(2)(A).[8]

8. On December 8, 2008, AstraZeneca filed a complaint against Handa in the United States District Court for the District of New Jersey, alleging that Handa's filing of its

[5] Stipulated Facts ¶ 26, ECF No. 156-1, *AstraZeneca Pharmaceuticals et al. v. Handa Pharmaceuticals LLC*, 3:10-cv-01835-JAP-TJB (D.N.J.).
[6] *Id.* ¶ 27.
[7] *Id.* ¶ 34.
[8] *Id.* ¶ 35

ANDA No. 90-482 relating to its 150mg strength of generic Seroquel XR infringed the '437 Patent under 35 U.S.C. § 271(e)(2)(A).[9]

9. The foregoing three lawsuits filed by AstraZeneca against Handa were consolidated, and are collectively referred to herein as the "Handa Seroquel XR Patent Litigation."

10. AstraZeneca filed two patent infringement lawsuits against Accord regarding the two Accord Paragraph IV certification notice letters. First, on September 26, 2008, AstraZeneca filed civil action no. 08-cv-04804 against Accord in the District of New Jersey in connection with Accord's notice letter dated September 5, 2008.[10] Second, on February 10, 2009, AstraZeneca filed civil action no. 09-cv-00619 against Accord in the District of New Jersey in connection with Accord's notice letter dated January 23, 2009. These lawsuits against Accord are collectively referred to as the "Accord Seroquel XR Patent Litigation."

11. Over the course of the Handa Seroquel XR Patent Litigation, it became clear that Handa's proposed generic version of Seroquel XR would not infringe the '437 Patent. The '437 Patent narrowly claimed very specific formulations of quetiapine fumarate, each of which requires a "gelling agent." Judge Joel A. Pisano, who presided over the Accord Seroquel XR Litigation and the Handa Seroquel XR Patent Litigation, construed "gelling agent" to mean "any substance which forms a gel when in contact with water." But Handa's proposed generic version of Seroquel XR used hydrogenated vegetable oil, which is hydrophobic, not even miscible with water, *i.e.,* it does not form a homogeneous mixture with water, and not a "gelling agent" under the district court's claim construction.

[9] *Id.* ¶ 36.
[10] *Id.* ¶¶ 37-38.

12. The District Court issued a claim construction opinion applicable in both the Handa Seroquel XR Patent Litigation and the Accord Seroquel XR Patent Litigation on November 30, 2010.

13. On December 9, 2010, the FDA granted tentative approval to Handa's ANDA for generic Seroquel XR in all strengths, determining that Handa's ANDA for generic Seroquel XR was approvable and satisfied all bioequivalence; chemistry, manufacturing, and controls ("CMC"); and labeling requirements.[11]

14. Under the District Court's claim construction, AstraZeneca was very likely to lose the litigation over the '437 Patent. Rather than face the risk that Handa's proposed generic versions of Seroquel XR would be found not to infringe the '437 Patent, AstraZeneca induced Handa with a large "reverse payment" (*i.e.*, a payment from the patent holder, AstraZeneca, to the alleged infringer, Handa), to quit the patent fight and not compete with AstraZeneca for up to five years.

15. Specifically, on or about September 29, 2011, AstraZeneca and Handa entered into a settlement agreement concerning Handa's ANDA No. 90-482 (the "Handa Non-Compete Agreement").[12] Under the terms of the Handa Non-Compete Agreement, Handa agreed to quit the patent fight and delay its launch of generic extended-release quetiapine fumarate in the 50mg, 150mg, 200mg, 300mg strengths until November 1, 2016 (and also agreed to quit the patent fight as to the 400mg strength as well, for which Handa was not the first filer). In exchange for Handa's delayed generic launch, AstraZeneca agreed not to

[11] *See AstraZeneca Pharm., LP v. Anchen Pharm., Inc.*, Civ. No. 10-cv-1835, 2012 WL 1065458, at *2, *40 (D.N.J. Mar. 29, 2012).
[12] *See* ECF No. 139, *AstraZeneca Pharmaceuticals et al. v. Accord Pharmaceuticals LLC*, 3:09-cv-00128-JAP-TJB (D.N.J.).

compete with Handa by launching an authorized generic Seroquel XR (the brand product packaged and sold as a generic, sometimes referred to as an "AG") during the first 180 days after Handa's launch, *i.e.*, between November 1, 2016 and April 30, 2017. But for the Handa Non-Compete Agreement, Handa would not have agreed to delay launching 50mg, 150mg, 200mg, 300mg strengths of generic Seroquel XR until November 1, 2016 and AstraZeneca would not have agreed to delay launching an authorized generic in these strengths to compete with Handa's generic product until May 1, 2017. The purpose and effect of the Handa Non-Compete Agreement was to delay lower-priced generic competition with AstraZeneca's branded Seroquel XR product for up to five years, and to eliminate competition for generic extended-release quetiapine fumarate from an AG in the 50mg, 150mg, 200mg, 300mg strengths during Handa/Par's 180-day period of generic exclusivity (as described below), thereby generating enormous windfalls for AstraZeneca and Handa (and eventually Par).

16. On October 29, 2012, Par announced that it had acquired Handa's ANDA No. 90482.[13] Par's press release stated that it:

> . . . entered into an exclusive acquisition and license agreement with Handa Pharmaceuticals, LLC to acquire Handa's Abbreviated New Drug Application (ANDA) for quetiapine fumarate extended-release tablets, the generic version of AstraZeneca's Seroquel XR®. Handa believes it is the first applicant to file an ANDA containing a paragraph IV certification for the 50 mg, 150 mg, 200 mg and 300 mg strengths of the product, which would potentially provide 180 days of marketing exclusivity . . . .
>
> Under the terms of the agreement, Par has made a payment for the ANDA and for exclusive rights to market, sell and distribute quetiapine fumarate extended-release tablets in the U.S. under the ANDA, subject to its final approval by the U.S. Food and Drug Administration. Par will receive a share of profits from the sales of the product. Under the terms of a prior settlement agreement with AstraZeneca, which has been assigned to Par, Par has a license to enter the U.S. market with quetiapine fumarate extended-release tablets on November 1, 2016 or earlier under certain circumstances.

[13] *See* Tentative Approval Letter from Keith Webber, Deputy Director Office of Pharmaceutical Science, FDA, to Maggie Chang, Executive Vice President, Quality Affairs, Handa Pharmaceuticals, LLC, at 1 (Dec. 9, 2010),

17. A press release Handa issued on May 10, 2017 confirms that Handa and Par agreed, as part of their acquisition and license agreement, to share in the illicit profits from their Handa Non-Compete Agreement. The press release states, "Par's Quetiapine XR ANDA was developed by Handa and acquired by Par on August 3, 2012. Handa retains the right to a portion of profits from the sale of the product, pursuant to its agreement with Par."[14] By acquiring Handa's ANDA, acquiring an assignment of the Handa Non-Compete Agreement, agreeing to divide the illicit gains therefrom, performing the delay provisions thereof, and selling generic Seroquel XR at *supra*-competitive prices, Par became an active participant and co-conspirator in the pre-existing conspiracy between Handa and AstraZeneca and Par is, like Handa and AstraZeneca, jointly and severally liable for all harm flowing from that illegal Agreegment.

18. Accord and AstraZeneca entered into an agreement (the "Alleged Non-Compte Agreement") similar to the Handa Non-Compete Agreement, which included a similar reverse payment from the patent holder, AstraZeneca, to the alleged infringer, Accord, to quit the patent fight and not compete with AstraZeneca for up to five years. Specifically, on or about October 5, 2011,[15] prior to the end of any trial, Accord and AstraZeneca entered into an agreement pursuant to which Accord agreed to delay its launch of the 400mg strength of generic Seroquel XR, for which Accord was the first ANDA filer, until November 1, 2016, and AstraZeneca agreed to not launch an authorized generic version of the 400mg strength for 180 days thereafter. Pursuant to this agreement, Accord in fact did not launch its generic

[14] *See generally* ECF No. 139, *AstraZeneca Pharmaceuticals et al. v. Accord Pharmaceuticals LLC*, 3:09-cv-00128-JAP-TJB (D.N.J.).

[15] *See US District Court Finds SEROQUEL XR Formulation Patent Valid and Infringed* (Mar. 29, 2012), https://www.businesswire.com/news/home/20120329006628/en/District-Court-Finds-SEROQUEL-XR-Formulation-Patent ("On September 29, 2011, AstraZeneca granted Handa a license to the 5,948,437 patent effective November 1, 2016, or earlier under certain circumstances.").

400mg Seroquel XR product until November 1, 2016, and AstraZeneca did not launch an authorized generic version of Seroquel XR 400mg until May 1, 2017.

19. But for the Accord Non-Compete Agreement, Accord would not have agreed to delay launching the 400mg strength of generic Seroquel XR until November 1, 2016 and AstraZeneca would not have agreed to delay launching an authorized generic in this strength to compete with Accord's generic product until May 1, 2017. The purpose and effect of the Accord Non-Compete Agreement was to delay lower-priced generic competition with AstraZeneca's branded Seroquel XR product for up to five years, and to eliminate competition for generic extended-release quetiapine fumarate from an AG during Accord's 180-day period of generic exclusivity, thereby generating enormous windfalls for AstraZeneca and Accord.

20. On November 1, 2016, Par began selling 50mg, 150mg, 200mg, 300mg generic Seroquel XR and Accord began selling 400mg generic Seroquel XR.[16]

21. On May 1, 2017 (180 days later), AstraZeneca launched authorized generic versions of Seroquel XR in the 50mg, 150mg, 200mg, 300mg, and 400mg strengths.[17]

22. Because of the unlawful Handa Non-Compete Agreement and Accord Non-Compete Agreement (together, the "Non-Compete Agreements"), no generic Seroquel XR was available for Plaintiff and other members of the Class (defined below) to purchase in the United States until November 1, 2016 and, for a period of six months thereafter, there was

[16] *See Par Pharmaceutical Acquires Rights to Market and Distribute Generic Seroquel XR® in the U.S.* (Oct. 29, 2012), https://www.prnewswire.com/news-releases/par-pharmaceutical-acquires-rights-to-market-and-distribute-generic-seroquel-xr-in-the-us-176239031.html

[17] *Handa Pharmaceuticals, Inc. Announces FDA Approval for Generic Version of AstraZeneca's SEROQUEL XR® Extended Release Tablets* (May 10, 2017), https://handapharma.com/handa-pharmaceuticals-inc-announces-fda-approval-for-generic-version-of-astrazenecas-seroquel-xr-extended-release-tablets/.

only one generic available for each strength of Seroquel XR (marketed by Par in the 50mg, 150mg, 200mg, and 300mg strengths and by Accord in the 400mg strength).

23. But for the unlawful Non-Compete Agreements, one or more generic versions of Seroquel XR (in each strength) would have entered the market much earlier – either following patent litigation victory by Handa and/or Accord, at-risk launch(es) by Handa and/or Accord, or agreement(s) that did not include unlawful reverse payments from AstraZeneca for delay. Courts have repeatedly recognized that payments for delay result in later generic entry dates. *See, e.g., In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751-52 (E.D. Pa. 2014). In addition, AstraZeneca would have simultaneously launched authorized generic Seroquel XR (in each strength) when generic entry occurred instead of waiting until after Handa/Par's and Accord's 180-day marketing exclusivity lapsed (as AstraZeneca actually did). Thus, absent the unlawful Non-Compete Agreements, Plaintiff and members of the Class would have been able to satisfy their requirements for extended-release quetiapine fumarate at significantly lower prices substantially earlier.

24. By and through the Non-Compete Agreements, AstraZeneca, Handa/Par and Accord agreed to divide ill-gotten revenues, both during the period in which Handa/Par and Accord agreed not to launch (*i.e.*, prior to November 1, 2016), and during Handa/Par's and Accord's 180-day periods of generic marketing exclusivity during which AstraZeneca agreed not to launch authorized generic Seroquel XR to compete with Handa/Par's and Accord's respective generic products, all of which resulted in anticompetitive overcharges to Plaintiff and members of the Class.

25. Defendants thus violated state antitrust and consumer protection laws through the anticompetitive Non-Compete Agreements that allocated markets, restricted output, and

improperly maintained, enhanced and extended AstraZeneca's market and monopoly power by (1) foreclosing or delaying competition from lower-priced generic Seroquel XR that otherwise would have entered the market earlier; (2) foreclosing or delaying competition from authorized generic Seroquel XR that otherwise would have entered the market earlier; and (3) fixing, raising, maintaining, or stabilizing the prices of Seroquel XR and its generic equivalents at *supra*-competitive levels.

26. Plaintiff and all others similarly situated were injured and sustained damages in the form of overcharges for branded and generic forms of Seroquel XR as a result of the unlawful Non-Compete Agreements. Plaintiff, on behalf of the Class (defined below), files this suit to recover these overcharges.

III. THE PARTIES

27. Plaintiff LEHB is a voluntary employee benefits plan organized pursuant to § 501(c) of the Internal Revenue Code to provide health benefits to its eligible participants and beneficiaries. LEHB's members are current and retired sworn Philadelphia Police Officers, Deputy Sheriffs, and County Detectives, and their dependents. LEHB was established pursuant to a duly executed Trust Agreement for the purpose of providing medical, surgical and hospital care or benefits, including dental, optical and prescription drug benefits, to approximately 23,000 beneficiaries and covered spouses and dependents. LEHB maintains its principal place of business in Philadelphia, Pennsylvania. LEHB paid for Seroquel XR in class state(s) during the Class period.

28. Defendant AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of Delaware, with a principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

29. Defendant AstraZeneca LP is a Delaware limited partnership with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

30. Defendant AstraZeneca UK Limited is a company operating and existing under the laws of the United Kingdom, with its principal place of business at 15 Stanhope Gate, London, United Kingdom W1Y 6LN.

31. Defendant Handa Pharmaceuticals, LLC is a limited liability corporation organized under the laws of California, with a principal place of business at 1732 N. 1st Street, Suite 200, San Jose, California 95112. As set forth in this Complaint, Handa assigned the Anticompetitive Agreements described herein to Par, which performed the agreements, sold generic Seroquel XR at *supra*-competitive prices, and shared the illicit gains with Handa.

32. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977.

33. Defendant Accord Pharmaceuticals, Inc. is a North Carolina corporation with its principal place of business at 1009 Slater Rd. Suite 210 B, Durham, NC 27703.

34. All of Defendants' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or undertaken by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with Defendants' actual and/or apparent authority.

IV. JURISDICTION AND VENUE

35. This Court has jurisdiction over this matter under 28 U.S.C. § 1332(d) because this action is a class action in which the aggregate amount in controversy for the proposed

class exceeds $5,000,000 and at least one Class Member (hereinafter defined) is a citizen of a state different from that of one of the Defendants.

36. This Court also has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367(a).

37. Venue is appropriate within this District under 28 U.S.C. § 1391. Defendants resided, transacted business, were found, or had agents within this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District.

38. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

39. During the Class Period (defined below), AstraZeneca, Par, Handa, and Accord manufactured, sold, and/or shipped Seroquel XR and/or generic Seroquel XR in a continuous and uninterrupted flow of interstate commerce. The contract and conspiracy in which Defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

40. During the Class Period, each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate the Non-Compete Agreements and conspiracy.

41. This Court has personal jurisdiction over each Defendant because each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of its illegal conduct and conspiracy throughout the United States, including in this District. The conduct and conspiracy have been directed at, and have had the

intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

V. REGULATORY BACKGROUND

A. THE REGULATORY STRUCTURE FOR APPROVAL OF DRUGS

42. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a company seeking to market a new drug must obtain the approval of the FDA by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-92. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as information on applicable patents. 21 U.S.C. §§ 355(a), (b).

43. When the FDA approves a brand manufacturer's NDA, the brand manufacturer may list in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations (called the "Orange Book") any patent that it certifies (1) claims either the approved drug product or approved methods of using the drug product, and (2) could reasonably be asserted against a generic manufacturer who makes, uses, or sells the drug product without authorization prior to the expiration of the listed patent(s). Relevant patents issued after NDA approval must be listed in the Orange Book within 30 days of issuance. 21 U.S.C. §§ 355(b)(1), (c)(2).

44. The FDA relies completely on the brand manufacturer's certification about its patents, as the FDA does not have the resources or authority to verify for accuracy or trustworthiness whether those patents are valid and enforceable, and actually cover the drug product or its use. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments

45. In 1984, Congress enacted the Hatch-Waxman Amendments to the FDCA to expedite the entry of less expensive generic competitors to brand drugs to reduce healthcare expenses nationwide, while also providing for patent term extensions and the ability to file pre-launch infringement suits to bolster pharmaceutical companies' financial incentives to create new and innovative products. *See generally* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

46. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historic revenues and profits for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1985, prescription drug revenue for brand and generic drugs totaled $21.6 billion; by 2013, total prescription drug revenue had climbed to more than $329.2 billion, with generic drugs accounting for 86% of prescriptions.[18] Generics are now dispensed 95% of the time when a generic form is available.[19]

47. The Hatch-Waxman Amendments simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's NDA. The ANDA

[18] *See* IMS INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SHIFTING COSTS OF HEALTHCARE, at 30, 51 (Apr. 2014), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/IMS-Medicine%20use%20and%20shifting%20cost%20of%20healthcare.pdf; Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 4 (July 1998).

[19] *Id.* at 51.

applicant must further show that the generic drug is bioequivalent (*i.e.*, that the active ingredient of the proposed generic drug is absorbed in the patient's blood stream to the same extent and for the same amount of time as the brand counterpart, 21 U.S.C. § 355(j)(8)(B)), and that it is pharmaceutically equivalent (*e.g.*, that it contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug). Generic drugs that are both bioequivalent and pharmaceutically equivalent are considered "therapeutically equivalent" to the brand drug. *See generally* 21 U.S.C. §355(j) *et seq*.

48. The FDCA and Hatch-Waxman Amendments operate on the proven scientific principle that therapeutically equivalent drugs are substitutable. Generic drugs that are therapeutically equivalent to their brand counterparts are given an "AB" rating by the FDA, a designation which causes a pharmacy presented with a prescription for the brand to automatically dispense the generic instead.

2. Paragraph IV Certifications

49. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

a. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

b. that the patent for the brand drug has expired (a "Paragraph II certification");

c. that the patent for the brand drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

d. that the patent for the brand drug is invalid, unenforceable, and/or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

50. To obtain FDA approval of an ANDA prior to the expiration of a patent or patents listed in the Orange Book, a generic manufacturer must file a Paragraph IV certification and serve timely notice to the brand manufacturer. The filing of an ANDA with a Paragraph IV certification gives rise to a cause of action for patent infringement pursuant to 35 U.S.C. § 271(e)(2). If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notice of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of thirty months (the "30-month stay"), or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). The FDA may grant tentative approval to an ANDA when it determines that the ANDA would otherwise be ready for final approval but for the existence of an unexpired patent for which the generic filer has submitted a Paragraph III certification (*i.e.*, that the generic does not intend to market the ANDA product prior to the expiration of the patent) or the existence of a regulatory exclusivity, such as the 30-month stay.

3. First-Filer's 180-Day Exclusivity Period

51. Generics may be classified as (1) first-filer generics, (2) later-filing generics, or (3) the brand's own authorized generic.

52. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first generic manufacturer who files an ANDA with a Paragraph IV certification (the "first-filer") a 180-day period to market the generic version of the drug, during which the FDA may not grant final approval to any other later-filing generic manufacturer's ANDA for the same brand drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). That is, when a first-filer files a substantially

complete ANDA with the FDA and certifies that at least one unexpired patent listed in the Orange Book as covering the brand product is either invalid, unenforceable, or not infringed by the generic's product, the FDA cannot approve a later-filing generic company's ANDA until that first-filer generic has been on the market for 180-days, or until the first-filer's 180-day exclusivity has been forfeited. The 180-day window is referred to as the first-filer's 180-day "exclusivity" or "exclusivity period."

53. By contrast, a first-filer that informs the FDA that it intends to wait until all Orange Book listed patents expire before marketing its product (*e.g.*, one that files a Paragraph III certification as to all Orange Book-listed patents) will not receive a 180-day exclusivity period. Congress created the 180-day exclusivity period to incentivize generic manufacturers to file Paragraph IV certifications challenging weak patents, or to invent around such patents by creating non-infringing generics.

54. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first-filer.[20]

55. An authorized generic, or AG, is simply the brand product, sold or licensed by the brand for sale, under generic trade dress, at a cheaper price than the brand price. Because the AG is already approved under the brand manufacturer's NDA, it can be marketed at any time, including during the first-filer's 180-day exclusivity period.[21]

56. A brand can also license a first-filer generic competitor to launch an authorized generic. The first-filer's launch of an authorized generic triggers its 180-day exclusivity period.

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[20] *FTC v. Actavis, Inc.*, 570 U.S. 136, 133 S. Ct. 2223, 2229 (2013) (internal citation and quotation marks omitted).

[21] *See, e.g.*, FDA, *Guidance for Industry, 180-Day Exclusivity: Questions and Answers*, January 2017 at 13, https://www.fda.gov/media/102650/download; ANDA Approval Letter from Carol Holquist, Deputy Director, Office of Regulatory Operations, FDA, to Meredith Selby, Senior Director, Regulatory Affairs, Par Pharmaceutical Inc., at 2 (May 9, 2017), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/090482Orig1s000ltr.pdf

57. If the only versions of a drug on the market are the brand and the first-filer's generic product, then the first-filer prices its product below the brand product, but above what it would if there was more than one generic (such as an authorized generic). The lack of competition from an authorized generic therefore inflates the price of a first-filer generic.

B. THE COMPETITIVE BENEFITS OF AB RATED GENERIC COMPETITION

58. Since the FDA deems AB-rated generic versions of brand drugs to be just as safe and effective as their brand counterparts, the only material mode of differentiating the two is their price. On average, generics are at least 10% less expensive than their brand counterparts when there is a single generic competitor. This discount typically increases to 50% - 80% (or more) when there are multiple generic competitors on the market for a given brand.

59. Every state has adopted laws that either require or permit pharmacies to automatically substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician has affirmatively requested the brand). Accordingly, once one generic equivalent enters the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the brand's sales within the first six months.

60. Within 12 months of entering the market, Federal Trade Commission ("FTC") found that on average, generics captured 90% of corresponding brand drug sales and (with multiple generics on the market) prices had dropped 85% relative to pre-entry brand prices.[22] That is because, once multiple generic competitors enter, the competitive process accelerates and multiple generic sellers typically compete vigorously with each other for market share by

[22] *See* FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS AT 8 (Jan. 2010) ("FTC Pay-for-Delay Study"), http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf

driving prices further down toward marginal manufacturing costs.[23] As a result, competition from generic drugs is viewed by brand drug companies, such as AstraZeneca, as a grave financial threat.

61. By contrast, generic competition enables purchasers (like Class members here) to purchase substantially cheaper generic versions of a drug instead of the more expensive brand, and to purchase generic versions of a drug at increasingly lower prices as more generic versions of that drug enter the market. In addition, generic competition enables purchasers to pay lower prices for the original branded drug when the brand company lowers its brand price to compete with the generic for sales.

62. Once exclusivity is lost and generic entry occurs – an event sometimes referred to as the "patent cliff" – the brand manufacturer can expect a significant drop in profits, as it is forced to either compete by dramatically lowering prices, or accept dramatically lower sales. The tradeoff of longer exclusivity rights in return for quick and effective generic entry after loss of exclusivity was fundamental to the policies and procedures that Congress established in the Hatch-Waxman Act, and embraced by the states in their generic substitution laws. "According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Billions more are saved when hospitals use generics."[24]

[23] *See*, *e.g.*, Patricia Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, J.L. & ECON. 311, 314, 339-41, 354-55 (Oct. 2000); Tracy Regan, *Generic Entry and Price Competition in the Prescription Drug Market--18 Years after the Waxman-Hatch Act* (Univ. of Miami, Dep't of Econ., Working Paper, Feb. 14, 2004); R. Frank, *The Ongoing Regulation of Generic Drugs*, NEW ENG. J. MED., v. 357, pp. 1993-96 & n.20 (Nov. 2007).

[24] *Generic Drugs Undergo Rigorous FDA Scrutiny*, U.S. Food & Drug Admin. (Oct. 8, 2014), https://www.fda.gov/consumers/consumer-updates/generic-drugs-undergo-rigorous-fda-scrutiny

C. BRAND AND GENERIC COMPANIES HAVE STRONG FINANCIAL INCENTIVES TO AGREE TO ANTICOMPETITIVE TERMS

63. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge *supra*-competitive prices. Brand manufacturers, such as AstraZeneca, are well aware of generics' rapid erosion of their brand sales, and thus seek to delay and stall the impact of generic competition for as long as possible, sometimes (as here) resorting to illegal means.

64. One way that brand manufacturers game the system to anticompetitive effect is by paying generic manufacturers to delay entering the market. These agreements not to compete are sometimes referred to as "reverse payment agreements," "exclusion payment agreements," or "pay-for-delay agreements," which have long concerned the FTC. Brand and generic manufacturers execute exclusion payment agreements to take advantage of the regulatory consequences associated with the generic manufacturers' Paragraph IV certifications.

65. In a typical exclusion payment agreement, the brand manufacturer pays a generic manufacturer to delay or abandon market entry. The brand manufacturer preserves its monopoly by effectively paying some of its monopoly profits to the generic manufacturer, which in turn agrees to delay marketing its product.

66. One method of payment to a first-filer generic company comes in the form of the brand company's promise to not launch an "authorized generic" version of the brand drug during the first-filer's 180-day exclusivity. As discussed above, an authorized generic is the brand drug, sold under the brand NDA, but sold by the brand or a licensee under generic trade dress. Because the brand manufacturer already has approval to sell its brand drug, it does not

need to file an ANDA or obtain any additional approval to market an authorized generic. Multiple courts have recognized that ANDA filers have no right to be free from competition from an authorized generic.

67. In a 2011 report issued at the request of Congress, the FTC concluded that no-authorized-generic promises were being used as a payment by brands to generics for delayed generic entry, noting that "there is strong evidence that agreements not to compete with an authorized generic have become a way for brand-name companies to compensate generic competitors for delaying entry."[25]

68. For the brand company, an authorized generic launched during the first-filer's 180-day exclusivity (or longer) provides a low-cost, low-risk means to regain some of the revenue lost from the patent-cliff. An authorized generic launch, however, has a huge negative impact on the first-filer's revenue. A first-filer generally earns about 80% of its total income from a given generic product during its exclusivity period. An authorized generic, when launched during that time, will capture 50% or more of total generic unit sales during that period,[26] and will cause generic prices to decrease as a result of the price competition.[27] A brand company's promise not to launch an authorized generic during the first-filer's 180-day exclusivity period is thus a very valuable payment to the first-filer, doubling the first-filer's

[25] FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT ("FTC, Authorized Generic Drugs") (August 2011) at vi, https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

[26] *Id.* at iii, vi, 41-48, 57-59.

[27] *Id.* at, *e.g.*, ii-iii, vi-vii, 40, 5 n.21 (citing IMS CONSULTING, IMS HEALTH, ASSESSMENT OF AUTHORIZED GENERICS IN THE U.S. (2006) (written for PhRMA) (Pharmaceutical Research and Manufacturers of America), http://replay.web.archive.org/20061009134405/http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report 6-22-06.pdf or http://208.106.226.207/downloads/IMSAuthorizedGenericsReport_6-22-06.pdf

unit sales and more than doubling its revenues and profits (by removing a source of price competition). Correspondingly, a brand company's promise not to launch an authorized generic represents a substantial sacrifice of the revenues and profits for the brand that the brand company would have otherwise earned by launching an authorized generic. Those revenues and profits are instead ceded, by way of the no-authorized generic promise, to the first-filer generic, who has no right to be free from competition from an authorized generic.

69. For a first-filer preparing to market a generic version of a brand product such as Seroquel XR, such as Handa/Par for the 50mg, 150mg, 200mg and 300mg strengths and Accord for the 400mg strength, the difference between (1) selling the only generic product for six months and (2) selling a generic product while competing against an authorized generic for the first six months of generic marketing, is substantial, and worth up to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry, and the FTC's authorized generic report cites numerous documents from industry participants confirming the financial impact of an authorized generic and, by necessary implication, its absence.

70. A no-authorized generic agreement between brand and generic drug companies – horizontal competitors – unjustly enriches both companies and injures consumers twice over: first, it prolongs the period during which only the high-priced brand is available; and second, it ensures that, even after delayed generic competition begins, generic prices are artificially inflated by the absence of a second generic competitor (the authorized generic).

71. Here, Handa/Par and Accord each agreed to delay competing in the market for Seroquel XR in exchange for AstraZeneca's promise not to launch authorized generic Seroquel XR in competition with Handa/Par's and Accord's generic Seroquel XR products during Handa/Par's and Accord's respective 180-day exclusivity periods. As set forth further below,

these promises not to launch authorized generic Seroquel XR, which were part of the Non-Compete Agreements, constituted large payments to each of Handa/Par and Accord for which there can be no redeeming procompetitive justification, because they represent illegal market allocation or output restriction agreements, and a no-authorized-generic promise lacks any cognizable procompetitive justification as a matter of law.

72. An anticompetitive agreement entered into between the brand and the first-filer generic often creates a bottleneck preventing the later ANDA filers from launching, since the later ANDA filers cannot launch earlier than 180 days after the first-filer's launch.

73. Later ANDA filers have more modest financial prospects than the first-filer generic because the later filers have no expectation of any form of market exclusivity, such as the first-filer's 180-day exclusivity. By the time the later ANDA filers enter the market, they typically must compete with the brand, the first-filer, an authorized generic, and other later filers.

74. Nevertheless, in the absence of an anticompetitive agreement between the brand company and the first-filer, the later ANDA filers have procompetitive incentives. They are motivated to enter the market as early as possible because the sooner they enter, the sooner they can earn profits by competing for sales in the market, which results in lower prices.

75. Later ANDA filers, however, cannot obtain final FDA approval to enter the market until the first-filer's 180-day exclusivity has run or been forfeited. An agreement between the brand and the first-filer that delays the first-filer's entry thus creates a bottleneck that, by delaying the first filer's 180-day exclusivity, consequently delays the later ANDA filers' entry as well.

76. Agreements causing such bottlenecks are fundamentally anticompetitive and are contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly profits by blocking and delaying access to more affordable generic drugs, forcing purchasers to buy the more-expensive brand drug instead.

VI. FACTUAL ALLEGATIONS

A. ASTRAZENECA'S SEROQUEL XR PATENTS

77. AstraZeneca Pharmaceuticals LP is the holder of NDA No. 22-047, under which the FDA granted approval for extended-release tablets containing various different dosage strengths of the active ingredient 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl] dibenzo [b,f] [1,4] thiazepine fumarate (salt), which is commonly referred to as quetiapine fumarate. AstraZeneca Pharmaceuticals LP markets these tablets in the United States under the trademark Seroquel® XR.

78. AstraZeneca Pharmaceuticals LP is the owner of U.S. Patent No. 4,879,288 ("the '288 Patent"). The '288 Patent issued on November 7, 1989 from United States Application No. 07/028,473, was filed on March 20, 1987. Although the '288 Patent was originally set to expire on March 20, 2007, it received a patent term extension ("PTE") of 1,651 days under 35 U.S.C. 156. Based upon the PTE, the '288 Patent expired on September 26, 2011.

79. AstraZeneca UK Limited is the owner of the '437 Patent. The '437 Patent issued on September 7, 1999 from United States Application No. 08/864,306, was filed on May 28, 1997. The '437 Patent expired on May 28, 2017.

80. AstraZeneca submitted the '288 and '437 Patents for listing in the FDA Orange Book under NDA No. 22-047. AstraZeneca Pharmaceuticals LP received pediatric

exclusivity[28] for NDA No. 22-047, and the pediatric exclusivity associated with the '288 and '437 Patents expired on March 26, 2012 and November 28, 2017, respectively.

81. Because the '288 Patent expired on September 26, 2011 and its pediatric exclusivity expired on March 26, 2012, neither the '288 Patent nor its associated pediatric exclusivity could have affected any generic drug company's right, ability or willingness to market a generic version of Seroquel XR after March 26, 2012.

82. The '437 Patent contains one independent claim and fourteen dependent claims. Each of the fourteen dependent claims in the '437 Patent incorporate the requirements of claim 1, including the requirement for a "gelling agent." "It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to be infringed." *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989). Accordingly, no generic drug company's ANDA or generic drug product could infringe the '437 Patent unless it contained, *inter alia*, a "gelling agent" as claimed in the '437 Patent.

B. HANDA AND ACCORD FILE ANDAS FOR GENERIC VERSIONS OF SEROQUEL XR

83. Handa and Accord were the first generic manufacturers to file ANDAs with the FDA containing Paragraph IV certifications regarding Seroquel XR patents.

84. Handa filed ANDA No. 90-482 for a generic version of extended-release quetiapine fumarate, and amended it four times, between spring and fall of 2008. On information and belief, Handa was the first applicant to file a substantially complete application containing a Paragraph IV certification for the 50mg, 150mg, 200mg, 300mg strengths, making Handa eligible for 180 days of regulatory exclusivity for those strengths of

[28] Congress enacted 35 U.S.C. § 355a to incentivize drug developers to conduct studies on their drugs in pediatric patients. Congress established as an incentive, that if the studies were successful, FDA would grant an additional 6-months of regulatory exclusivity running after patent expiration, during which the FDA would not approve generic versions of the studied drug

generic Seroquel XR. Handa's ANDA also included a Paragraph IV certification for the 400mg strength, although Handa was not the first applicant to file a substantially complete application containing a Paragraph IV certification for the 400mg strength.

85. Accord filed ANDA No. 90-681 for a generic version of extended-release quetiapine fumarate on June 18, 2008.[29] On information and belief, Accord was the first applicant to file a substantially complete application containing a Paragraph IV certification for the 400mg strength of extended-release quetiapine fumarate, making Accord eligible for 180 days of regulatory exclusivity for that strength of generic Seroquel XR.

86. Because Handa and Accord were the first companies to file substantially complete ANDAs with Paragraph IV certifications, they each stood to receive a significant and potentially highly profitable benefit under 21 U.S.C. 355(j)(5)(B)(iv): 180-days of marketing exclusivity during which the FDA would not give final approval to any other ANDA filer's generic equivalent of Seroquel XR.

87. After receiving confirmation of receipt from the FDA for their ANDAs, Handa sent four separate Paragraph IV notice letters to AstraZeneca of its ANDA, each containing Paragraph IV certifications that included a detailed statement of the factual and legal basis as to why the '437 Patent was invalid, unenforceable, and/or not infringed by Handa's ANDA products. The Paragraph IV notice letters included an offer of confidential access to Handa's ANDA, as required under the Hatch-Waxman Act. The notice letters were dated July 10, 2008, July 23, 2008, October 16, 2008, and November 14, 2008. The notice letters gave rise to an artificial act of infringement for purposes of creating standing, thereby allowing AstraZeneca to bring a cause of action for infringement against Handa under the Hatch-Waxman Act.

[29] Paragraph IV Patent Certifications June 18, 2019, https://www.fda.gov/media/82686/download.

88. Similarly, Accord sent AstraZeneca two separate Paragraph IV notice letters dated September 5, 2008 and January 23, 2009.[30] Accord's Paragraph IV certifications were required by statute to include "a detailed statement of the factual and legal basis of the opinion of the applicant that ['437 Patent] is invalid or will not be infringed," by Accord's generic Seroquel XR products.[31] On information and belief, Accord's Paragraph IV notice letters also included an offer of confidential access to Accord's ANDA as required under the Hatch-Waxman Act. The notice letters gave rise to an artificial act of infringement for purposes of creating standing, thereby allowing AstraZeneca to bring a cause of action for infringement against Accord under the Hatch-Waxman Act.

C. THE SEROQUEL XR PATENT LITIGATIONS

89. AstraZeneca filed three patent infringement lawsuits against Handa in response to Handa's Paragraph IV certification notice letters. First, in response to Handa's notice letters dated July 10, 2008 and July 23, 2008, AstraZeneca filed civil action no. 08-cv-3773 in the District of New Jersey on July 28, 2008. Second, on October 28, 2008, AstraZeneca filed civil action no. 08-cv-5328 in the District of New Jersey in response to Handa's notice letter dated October 16, 2008. Third, on December 8, 2008, AstraZeneca filed civil action no. 08-cv-5997 in the District of New Jersey in response to Handa's notice letter dated November 14, 2008.

90. AstraZeneca filed two patent infringement lawsuits against Accord in response to Accord's Paragraph IV certification notice letters. First, on September 26, 2008, AstraZeneca filed civil action no. 08-cv-04804 against Accord in the District of New Jersey in response to Accord's notice letter dated September 5, 2008. Second, on February 10, 2009,

[30] Stipulated Facts ¶ 27, ECF No. 156-1, *AstraZeneca Pharmaceuticals et al. v. Handa Pharmaceuticals LLC*, 3:10-cv-01835-JAP-TJB (D.N.J.).
[31] 21 U.S.C. § 355(j)(2)(B)(iv)(II).

AstraZeneca filed civil action no. 09-cv-00619 against Accord in the District of New Jersey in response to Accord's notice letter dated January 23, 2009.

91. Several generic drug companies in addition to Handa and Accord filed ANDAs seeking approval of generic versions of Seroquel XR ("the Later-Filing Generics"). AstraZeneca subsequently filed seven patent infringement lawsuits relating to generic Seroquel XR against four of the Later-Filing Generics in the District of New Jersey. On April 8, 2010, AstraZeneca filed civil action no. 10-cv-1835 against Anchen Pharmaceuticals, Inc. and Anchen, Inc. (together, "Anchen"). On August 16, 2010, AstraZeneca filed civil action no. 10-cv-4203 against Osmotica Pharmaceutical Corporation ("Osmotica"). Also on August 16, 2010, AstraZeneca filed civil action no. 10-cv-4205 against Torrent Pharmaceuticals Limited and Torrent Pharma Inc. (together, "Torrent"). On September 28, 2010, AstraZeneca filed civil action no. 10-cv-4971 against Torrent. On October 22, 2010, AstraZeneca filed civil action no. 10-cv-5519 against Mylan Pharmaceuticals, Inc. and Mylan, Inc. (together, "Mylan"). On April 29, 2011, AstraZeneca filed civil action no. 11-cv-2483 against Mylan. Also on April 29, 2011, AstraZeneca filed civil action no. 11-cv-2484 against Osmotica. The foregoing seven patent infringement lawsuits are referred to herein as "the Later-Filer Seroquel XR Patent Litigation."

92. The Handa Seroquel XR Patent Litigation, the Accord Seroquel XR Patent Litigation, and the Later-Filer Seroquel XR Patent Litigation are referred to collectively as "the Seroquel XR Patent Litigation."

93. During claim construction proceedings in the Seroquel XR Patent Litigation, the district court construed the term "gelling agent" as "any substance which forms a gel when in contact with water."[32]

94. On information and belief, the 30-month stay preventing final FDA approval of Handa's ANDA expired no later than April 2011.

95. On information and belief, the 30-month stay preventing final FDA approval of Accord's ANDA expired no later than July 2011.

96. On or about September 29, 2011, as further described below, AstraZeneca reached a settlement with Handa resolving the Handa Seroquel XR Patent Litigation. As a result, some or all of Handa's defenses in the Handa Seroquel XR Patent Litigation were never adjudicated.

97. On or about October 5, 2011, AstraZeneca reached a settlement with Accord resolving the Accord Seroquel XR Patent Litigation. As a result, on information and belief, some or all of Accord's defenses in the Accord Seroquel XR Patent Litigation were never adjudicated.

D. HANDA'S UNADJUDICATED DEFENSES WERE MERITORIOUS

98. Handa successfully designed around the '437 Patent by developing a non-infringing product that did not contain a "gelling agent" as required by each of the claims of the '437 Patent. Instead of using a hydrophilic "gelling agent," Handa's products used a hydrophobic compound known as hydrogenated vegetable oil ("HVO"). As explained below, Handa obtained a patent on its novel formulation despite the '437 Patent, reflecting the

[32] *See AstraZeneca Pharm., LP v. Anchen Pharm., Inc.*, Civ. No. 10-cv-1835, 2012 WL 1065458, at *2 (D.N.J. Mar. 29, 2012).

determination of the United States Patent and Trademark Office ("PTO") that Handa's formulation was patentably distinct from the formulation claimed in the '437 Patent.

99. On July 24, 2008, Handa filed United States Provisional Application No. 61/083,270 ("the '270 Application"). On September 5, 2008, Handa filed United States Application Serial No. 12/205,356 ("the '356 Application"), which claimed the benefit of the filing date of the '270 Application. On May 8, 2012, the '356 Application was issued as United States Patent No. 8,173,637 ("the Handa '637A Patent"). On March 28, 2011, Handa filed United States Application Serial No. 13/073,873 ("the '873 Application"), which claimed the benefit of the filing date of the '356 and '270 Applications. On August 23, 2011, the '873 Application was issued as United States Patent No. 8,003,637 ("the Handa '637B Patent").

100. Handa disclosed the '288 and '437 Patents as prior art in the applications that led to the Handa '637A Patent and Handa '637B Patent. By issuing the Handa '637A Patent and Handa '637B Patent despite AstraZeneca's '288 and '479 Patents, the examiner necessarily determined that the claimed compositions in the Handa '637A Patent and in the Handa '637B Patent were patentably distinct from the compositions disclosed and claimed in AstraZeneca's '288 and '479 Patents.

101. As Handa's own patents explain, HVO is a "hydrophobic" material that is "non-gelling":

> Examples of ***hydrophobic*** materials that can be used to form a ***non-gelling*** or non-swelling controlled release matrix for the atypical antipsychotic drug include beeswax, white wax, emulsifying wax, ***hydrogenated vegetable oil***...[33]

[33] '637A Patent at 6:24-39 (emphasis added).

102. The district court's claim construction in the Seroquel XR Patent Litigation requires that, *inter alia*, the "gelling agent" interact with "water" to "form[] a gel" (*see supra*); accordingly, one of the important characteristics in determining whether a particular compound is a "gelling agent" is whether it is "hydrophilic" (*i.e.*, water loving) or "hydrophobic" (*i.e.*, water hating). This is so because "hydrophobic" compounds such as HVO generally do not interact with water. Indeed, the '437 Patent itself indicates that the claimed "gelling agent" must be "hydrophilic": "The term gelling agent as used herein means any substance, ***particularly a hydrophilic substance***, which forms a gel when in contact with water. . . ."[34]

103. Had Handa not settled with AstraZeneca, Handa would have prevailed on its non-infringement defense. In addition, on information and belief, Handa had other meritorious defenses.

104. On or about September 29, 2011, AstraZeneca and Handa entered into the Handa Non-Compete Agreement.[35]

105. On or about October 5, 2011, AstraZeneca and Accord entered into the Accord Non-Compete Agreement.[36]

106. Under the terms of the Non-Compete Agreements, Handa and Accord respectively agreed to quit their patent fights and delay their respective generic Seroquel XR launches until November 1, 2016. In exchange for Handa's and Accord's agreements to delay

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[34] '437 Patent at 2:43-45 (emphasis added).

[35] *See US District Court Finds SEROQUEL XR Formulation Patent Valid and Infringed*, https://www.businesswire.com/news/home/20120329006628/en/District-Court-Finds-SEROQUEL-XR-Formulation-Patent (March 29, 2012), ("On September 29, 2011, AstraZeneca granted Handa a license to the 5,948,437 patent effective November 1, 2016, or earlier under certain circumstances.").

[36] *See AstraZeneca enters into a settlement agreement with Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd regarding US SEROQUEL XR® patent litigation (Oct. 5, 2011), https://www.astrazeneca.com/media-centre/press-releases/2011/AstraZeneca-enters-into-a-settlement-agreement-with-Accord-Healthcare-Inc-and-Intas-Pharmaceuticals-Ltd-regarding-US-SEROQUEL-XR-patent-litigation-05102011.html#modal-historic-confirmation*

launching, AstraZeneca agreed not to compete with Handa or Accord by launching an authorized generic for the first six months after their launches, *i.e.*, AstraZeneca agreed not to launch an authorized generic until May 1, 2017. The purpose and effect of the Non-Compete Agreements was to prevent AstraZeneca from facing lower-priced generic competition for up to five years and to allow Handa and Accord to sell generic Seroquel XR without competition from authorized generic Seroquel XR for six months after Handa's and Accord's November 1, 2016 generic Seroquel launches, from November 1, 2016 through April 30, 2017.

107. On October 29, 2012, Par announced that it had acquired Handa's ANDA No. 90-482. As part of Par's acquisition of Handa's ANDA, Handa assigned the Handa Non-Compete Agreement to Par. As explained above, Par became an active participant and co-conspirator in the pre-existing conspiracy between Handa and AstraZeneca and is jointly and severally liable for all harm flowing from the conspiracy.

108. AstraZeneca always intended to launch an authorized generic to compete with Handa/Par's and Accord's generic Seroquel XR products, as evident from the fact that AstraZeneca actually did so on the first day it was allowed to under the terms of the Non-Compete Agreements.[37] But for the Non-Compete Agreements, AstraZeneca would have launched authorized generic Seroquel XR at the time that Handa/Par and Accord launched, and competed for generic Seroquel XR sales during Handa/Par's and Accord's 180-day exclusivity periods. Instead, because of the Non-Compete Agreements, AstraZeneca waited 180 days after Handa/Par's and Accord's generic Seroquel XR launches to launch competitive authorized generic Seroquel XR.

[37] DailyMed, LABEL: QUETIAPINE FUMARATE EXTENDED RELEASE, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7283b14f-023d-466f-a7eb-4356803d7c65&audience=consumer (showing AstraZeneca with a May 1, 2017 launch date as an "NDA Authorized Generic").

109. Accord received FDA tentative approval from the FDA for its ANDA No. 90-0681 on December 14, 2010 and final approval on November 1, 2016.[38] On information and belief, Accord's 400mg generic Seroquel XR product would have received final approval before November 1, 2016 absent the Accord Non-Compete Agreement. Handa received tentative approval from FDA on December 9, 2010.[39] Par obtained final FDA approval for ANDA No. 90-482 on May 9, 2017, almost exactly the end of its 180-day exclusivity period.[40] On information and belief, absent the Handa Non-Compete Agreement, Handa/Par's 50mg, 150mg, 200mg and 300mg strengths of generic Seroquel XR would have received final FDA approval before November 1, 2016. Handa's and Accord's tentative FDA approvals meant that their ANDAs were ready for FDA final approval but for the existence of a patent or regulatory barrier.

110. On information and belief, AstraZeneca provided Handa/Par and Accord with licenses under its '437 Patent, and reverse payments in the form of agreements not to launch authorized generic versions of Handa/Par's and Accord's respective strengths of generic Seroquel XR ("no-AG provisions" or "no-AG promises"). AstraZeneca was motivated to make these reverse payments because it was a preferable alternative to AstraZeneca than risking an adverse ruling on its patent, which would have caused earlier generic Seroquel XR entry.

111. But-for the Non-Compete Agreements, Par/Handa and Accord would have been ready, able, and willing to launch their respective strengths of generic Seroquel XR much

[38] *See* Final Approval Letter from Carol Holquist to Sabita Nair, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/090681Orig1s000TAltr.pdf

[39] *See* Tentative Approval Letter from Keith Webber to Maggie Chang at 1, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/090482s000ltr.pdf

[40] *Handa Pharmaceuticals, Inc. Announces FDA Approval for Generic Version of AstraZeneca's SEROQUEL XR® Extended Release Tablets* (May 10, 2017), https://handapharma.com/handa-pharmaceuticals-inc-announces-fda-approval-for-generic-version-of-astrazenecas-seroquel-xr-extended-release-tablets/

earlier. Handa/Par's and Accord's generic Seroquel XR products would have received final approval from FDA upon (1) the conclusion of the 30-month stays; (2) litigation victory by Handa/Par and Accord earlier than November 1, 2016; or (3) a licensed generic Seroquel XR entry date earlier than November 1, 2016 pursuant to agreement(s) with AstraZeneca that did not include unlawful reverse payments from AstraZeneca to induce delay. *See, e.g.*, *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 405 (3d Cir. 2015) ("when the parties' settlement includes a [payment], the generic also presumably agrees to an early entry date that is later than it would have otherwise accepted."); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d at 751-52 (a reverse payment "is likely to induce the generic to agree to enter the market at a date later than that to which it would otherwise agree").

112. By on or about September 29, 2011, when the Handa Non-Compete Agreement was executed, Seroquel XR was generating nearly a billion dollars per year in revenues for AstraZeneca. Losing a substantial portion of that revenue stream in the event Handa and/or Accord were to prevail on non-infringement or other defenses – or in the event that AstraZeneca had not induced Handa and/or Accord with reverse payments to agree to delay launching generic Seroquel XR for 5 years – would have drastically reduced AstraZeneca's profits. Thus, AstraZeneca had enormous incentives to avoid competition from Handa and Accord by entering into the Non-Compete Agreements.

113. On information and belief, the Non-Compete Agreements contained confidentiality provisions precluding the parties to those agreements from disclosing the key terms of the Non-Compete Agreements, including AstraZeneca's covenants not to launch an authorized generic of Seroquel XR during Handa/Par's and Accord's 180-day exclusivity periods to compete with Handa/Par and Accord (the no-AG provisions). Although the parties

subsequently made vague public references to their Non-Compete Agreements, they concealed the agreements' anticompetitive purpose and terms. No public reference to the Non-Compete Agreements disclosed that AstraZeneca agreed not to compete with an authorized generic during Handa/Par's or Accord's 180-day exclusivity periods.

114. Nor did the parties' disclosures admit that the Non-Compete Agreements each included an agreed-upon anticompetitive no-authorized-generic provision as a *payment* from AstraZeneca to Handa/Par and to Accord in order to induce Handa/Par and Accord to delay generic Seroquel XR entry until November 1, 2016. Until that time, it was not knowable that Handa/Par's and Accord's generic Seroquel XR entry dates were affected (delayed) by payments (AstraZeneca's no-authorized generic promises). This was a deliberate concealment.

115. AstraZeneca's waiting to launch authorized generic Seroquel XR until Handa/Par's and Accord's 180-day exclusivities expired did not make economic sense. It would have been more lucrative for AstraZeneca to have simply launched authorized generic Seroquel XR immediately upon Handa/Par's and Accord's launches. AstraZeneca only agreed to delay its authorized generic launch until May 1, 2017, 180 days after Handa/Par and Accord launched generic Seroquel XR, as a *quid pro quo* for Handa/Par's and Accord's respective agreements to delay generic Seroquel XR competition until November 1, 2016.

116. On information and belief, as consideration for Handa/Par's and Accord's agreement to forgo selling generic extended-release quetiapine fumarate in competition with AstraZeneca's branded Seroquel XR for up to five years, AstraZeneca agreed to share with Handa/Par and Accord the monopoly profits from sales of branded Seroquel XR in the form of covenants not to compete with Handa/Par's and Accord's generics with authorized generic

Seroquel XR. Instead of competing, which would have resulted in lower prices of both generic and branded Seroquel XR, AstraZeneca agreed and conspired with Handa/Par and with Accord to maintain the prices of extended-release quetiapine fumarate at *supra*-competitive levels.

117. The Non-Compete Agreements benefitted Handa/Par and Accord by guaranteeing that they would be the sole generic seller on the market for their respective strengths during their 180-day exclusivity periods, which significantly increased Handa/Par's and Accord's anticipated sales revenues during their exclusivity periods because: (1) Handa/Par and Accord would capture all of the sales that would otherwise have gone to competing authorized generic Seroquel XR, and (2) Handa/Par and Accord would be able to charge significantly higher prices for their generic Seroquel XR products without price competition from competing authorized generic Seroquel XR.

118. A brand company's launch of a competing authorized generic is extremely costly to any first-filer generic, such as Handa/Par and Accord, because the authorized generic erodes the first-filer's share of the overall generic volume *and* pushes down generic prices. The authorized generic also cuts into the first-filer's long-term "first mover advantage," *i.e.*, the continuing market advantage that can accrue to the first entrant. As the FTC noted in a June 2009 report on authorized generics, "consumers benefit and the healthcare system saves money during the 180-day exclusivity period when an [authorized generic] enters the market, due to the greater discounting that accompanies the added competition provided by the [authorized generic]."[41] Thus, AstraZeneca's covenants not to launch authorized generic Seroquel XR

[41] FTC, Authorized Generic Drugs at ii.

during Handa/Par's and Accord's exclusivity periods were extremely valuable to Handa/Par and Accord.

119. Relatedly, AstraZeneca sacrificed large profits through its agreements not to launch authorized generics of Handa/Par's and Accord's respective strengths of generic Seroquel XR. Absent the unlawful Non-Compete Agreements, it would make economic sense for AstraZeneca to launch authorized generics during Handa/Par's and Accord's 180-day marketing exclusivity periods so that AstraZeneca would retain 50% of the sales that Handa/Par's and Accord's less expensive generics otherwise would otherwise capture.

120. As alleged above, an authorized generic typically captures approximately 50% of the generic unit sales during the first 180-days of generic marketing. Thus, AstraZeneca's promise to not launch an authorized generic Seroquel XR (the no-AG provision) constituted very large payments to Handa/Par and Accord.

121. Specifically, U.S. sales of Seroquel XR for the four dosage strengths for which Par was the first-filer (the 50mg, 150mg, 200mg and 300mg strengths) were, as expected, approximately $911 million for the 12 months ending September 30, 2016.[42] Thus Defendants could assume that 6 months (or half a year) of brand sales (the duration of AstraZeneca's covenant not to launch an authorized generic) would generate revenue of approximately $455.5 million (half of AstraZeneca's $911 million in annual Seroquel XR revenue).

122. As is common in the pharmaceutical industry, the generic is expected to take 80% (or more) of the brand sales over the first six months following generic entry. Thus, approximately $364.4 million worth of brand sales would be converted to the generic

[42] Handa Pharmaceuticals Announces Endo Begins Shipping Generic Version of AstraZeneca's SEROQUEL XR® (Nov. 1, 2016), https://handapharma.com/announcement-for-generic-shipment/

($455.5 million X 0.8) during the period of Handa/Par's 180-day exclusivity (the duration of AstraZeneca's covenant not to launch an authorized generic). As is also common, with only one generic on the market, that generic is typically priced at 90% of the brand, which would result in generic sales of approximately $327.96 million ($364.4 million X 0.9). Thus, the generic Seroquel XR sales revenue that would have reasonably been anticipated by Handa/Par during the 180-day exclusivity period without competition from an AG would be approximately $327.96 million.

123. Handa/Par's expectations would have differed dramatically if AstraZeneca had not promised to refrain from competing with authorized generic Seroquel XR. According to an FDA study of the effects of additional generic competitors on the generic price, the entry of a second generic drives the average generic price down to 52% of the brand price.[43] Thus, while the generics would still take 80% of six months of brand sales, or $364.4 million, the generic sales value would drop to $189.488 million ($364.4 million X 0.52). And, it would reasonably be expected that those sales would be split evenly between Handa/Par and AstraZeneca's authorized generic.[44] Thus, without the no-AG promise in the Handa Non-Compete Agreement, Handa/Par's sales of generic Seroquel XR during the first 6 months would be expected to be approximately $94.744 million ($189.488 million X 0.5).

124. As a result, the expected value at the time of the Handa Non-Compete Agreement to Handa/Par of the no-AG provision versus facing competition from an AG would have been as much as approximately $233.216 million, the difference between the

[43] https://www.fda.gov/about-fda/center-drug-evaluation-and-research/generic-competition-and-drug-prices

[44] [50] FTC, Authorized Generic Drugs at vi (The Federal Trade Commission has concluded that, when free from competition from an authorized generic, "the first-filer's revenue will approximately double" during the first six months of generic competition, compared to what the first filer would make if it faced authorized generic competition.).

amount Handa/Par would reasonably expect to earn as the only generic seller on the market for 180 days following launch and the amount it would reasonably expect to earn if it faced competition from an AG during this 180-day period ($327.96 million - $94.744 million). Thus, AstraZeneca's agreement to not launch an AG for 6 months following Handa/Par's generic launch was a payment to Handa/Par of as much as approximately $233.216 million. The value of this payment to Handa/Par was tantamount to AstraZeneca handing this amount to Handa/Par in cash.

125. The same math and reasoning applies to Accord. Specifically, in exchange for Accord's commitment to not launch its generic version of 400mg strength Seroquel XR until November 1, 2016, AstraZeneca promised Accord that it would not launch an authorized generic version of 400mg strength Seroquel XR until May 1, 2017. AstraZeneca's sales of the 400mg strength of Seroquel XR in 2015 (the last full calendar year before generic Seroquel XR entry) were, as expected, approximately $421 million. Using the same math as used for Handa/Par, the promise from AstraZeneca to Accord to not compete during Accord's 180-day exclusivity period was worth approximately $107.78 million.[45]

126. AstraZeneca often competes with first-filers by launching authorized generics. The FTC has found that, in the time period from 2001 to 2008, only four companies launched more authorized generics than AstraZeneca.[46]

127. It is economically rational for a brand manufacturer that intends to compete for generic sales by launching an authorized generic to do so contemporaneously with the first ANDA filer's launch. This is because, during the first-filer's 180-day exclusivity, the only

[45] Specifically, Accord's revenues without facing an AG would be expected to be $421 million X .5 X .8 X .9, or $151.56 million. Accord's revenues if it competed with an AG would be expected to be $421 million X .5 X .8 X .52 X .5, or $43.78 million. The difference is $107.78 million ($151.56 million - $43.78 million).

[46] FTC, Authorized Generic Drugs at 16 ("For each company, the graph includes all AGs marketed pursuant to the company's NDAs, whether marketed internally (e.g., by a subsidiary), or through an external generic partner.").

possible competitors for generic sales are the first-filer and the brand's authorized generic. No later-filing generic can launch during this time. As the Third Circuit observed, "Absent a no-AG promise, launching an authorized generic would seem to be economically rational for the brand." *King Drug Co. of Florence, Inc.*, 791 F.3d at 405.

128. Thus, it would have been economically rational for AstraZeneca to have launched authorized generic Seroquel XR contemporaneously with market entry by Handa/Par and Accord instead of *after* Handa/Par's and Accord's 180-day exclusivity periods. In the absence of the anticompetitive Non-Compete Agreements, AstraZeneca would have done so. Specifically, absent the Handa Non-Compete Agreement, AstraZeneca would have launched authorized generic Seroquel XR in the 50mg, 150mg, 200mg and 300mg strengths contemporaneous with Handa/Par's launch of generic Seroquel SR in these same strengths. Absent the Accord Non-Compete Agreement, AstraZeneca would have launched authorized generic Seroquel XR in the 400mg strength contemporaneous with Accord's launch of generic Seroquel XR in the 400mg strength.

129. Conversely, if there were no agreements preventing AstraZeneca from launching immediately upon Handa/Par's and Accord's launches, then AstraZeneca's waiting until Handa/Par's and Accord's 180-day exclusivity periods expired to launch authorized generic Seroquel XR was economically irrational. This is because there was no economically rational reason for AstraZeneca to forgo its AG Seroquel XR launches and forgo competing with Handa/Par and Accord during Handa/Par's and Accord's 180-day exclusivity periods. During the 180-day exclusivity period, AstraZeneca was permitted to launch an authorized generic which would only have to compete with a single generic competitor in each strength. But after expiry of Handa/Par's and Accord's 180-day exclusivity periods, other generics could

and would launch and AstraZeneca's AG would have to compete with those other generics too. Thus, it only made sense for AstraZeneca to forego its authorized generic launch during Handa/Par's and Accord's 180-day exclusivity periods as part of anticompetitive market-allocation or output-restriction agreements to compensate Handa/Par and Accord for delaying generic Seroquel XR competition.

130. The payments flowing from AstraZeneca to Handa/Par and to Accord via the Non-Compete Agreements' no-AG provisions had a cash value of approximately $233.216 million to Handa/Par and $107.78 million to Accord. AstraZeneca intended that these payments would induce Handa/Par and Accord to stay out of the market for Seroquel XR and its generic equivalents in return for sharing monopoly profits, a naked market allocation or output restriction agreement. The reverse payments from AstraZeneca to Handa/Par and Accord are unjustified, and Defendants had no procompetitive justification or other legitimate explanation for the payments. It is well established that there is no conceivable procompetitive justification for a covenant to delay the launch of authorized generics.

131. Absent AstraZeneca's unlawful reverse payments to Handa/Par and Accord, any agreement resolving AstraZeneca's patent infringement claim would have resulted in far less (or no) delay of Handa/Par's and Accord's generic Seroquel XR entry, generic competition would have been more robust, and generic prices would have been lower. But for the Non-Compete Agreements, Handa/Par and Accord would have launched their respective strengths of generic Seroquel XR earlier: at risk, following a patent litigation victory, or pursuant to a negotiated entry date as part of an agreement that did not include reverse payments.[47] At the same time, AstraZeneca would have competed for generic Seroquel XR

[47] As the Supreme Court stated, brand and generic companies can settle without reverse payments. "They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's

sales by immediately launching authorized generic Seroquel XR instead of waiting to launch its authorized generic Seroquel XR for 6 months following Handa/Par's and Accord's generic launches.

132. On information and belief, and based on the fact that several Later-Filing Generics actually launched 180 days after Handa/Par and Accord, several other Later-Filing Generics had agreements with AstraZeneca that permitted entry upon Handa/Par's and Accord's launch, subject to Handa/Par's and Accord's 180-day exclusivity periods. Had Handa/Par and Accord launched their respective strengths of generic Seroquel XR earlier, those Later-Filing Generics would have launched earlier as well. But for the bottleneck of generic competition caused by the Non-Compete Agreements, and more specifically by those agreements' foreseeable and intentional effect of causing Handa/Par's and Accord's 180-day exclusivity periods to remain untriggered and thus unelapsed for up to five additional years, until November 1, 2016, one or more Later-Filing Generics, would have launched earlier, along with Handa/Par's generic, Accord's generic, and the authorized generic, lowering generic Seroquel XR prices further still.

133. The reason that Handa/Par and Accord did not launch earlier than November 1, 2016 had nothing whatsoever to do with any purported infringement risk flowing from the '437 Patent. Rather, Handa/Par's and Accord's generic launches were delayed by the anticompetitive Non-Compete Agreements, just as Defendants understood and intended. In addition, Handa/Par and Accord, as the first ANDA filers for their respective strengths, had 180 days of regulatory exclusivity for those strengths during which no subsequent filer could launch an ANDA version of Seroquel XR. Thus, Handa/Par, Accord and AstraZeneca all

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market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Actavis*, 133 S. Ct. at 2237.

recognized that delaying Handa/Par's and Accord's generic launches in exchange for no-AG covenants would benefit each of them. AstraZeneca would benefit by continuing to charge monopoly prices for Seroquel XR almost until the '437 Patent's expiry despite the weakness of the '437 Patent. This is because Handa/Par and Accord were willing to be paid to delay their generic launches, and Handa/Par's and Accord's delay would delay the triggering, and thus the elapsing, of the Handa/Par's and Accord's 180-day exclusivity periods, thereby bottlenecking all generic Seroquel XR competition. Handa/Par and Accord benefitted by securing no-AG promises, allowing them to be free from AG competition for the first six months after their delayed generic Seroquel XR launches.

134. According to information available publicly through the FDA, in addition to first-filers Handa/Par and Accord, at least 12 additional companies filed ANDAs to sell generic Seroquel XR: Alignscience Pharma Inc., Anchen, Aurobindo Pharma Ltd., IntellipharmaCeutics Corp., Lupin Ltd., Macleods Pharmaceuticals Ltd., Mylan, Novast Laboratories, Osmotica, Pharmadex Ind., Scigen Pharmacenticals Inc. and Torrent.

135. According to information available publicly through the FDA, many of these entities received final approval on or around the end of Handa/Par's and Accord's actual 180-day exclusivity periods. These included Pharmadax Inc., IntellipharmaCeutics Corp., Accord (as to the 150mg, 200mg and 300mg strengths), Par (as to the 400mg strength) and Lupin Ltd. These approvals would have been granted earlier if Handa/Par's and Accord's 180-day exclusivity periods had been triggered (and elapsed) earlier as a result of Handa/Par and Accord launching generic Seroquel XR earlier, which would have occurred absent AstraZeneca's payments to Handa/Par and to Accord to delay competition (*i.e.*, absent AstraZeneca's no-AG promises).

136. But for the Defendants' ongoing performance under the Non-Compete Agreements, generic competition for Seroquel XR, including competition from authorized generic Seroquel XR, would have occurred earlier, and prices for extended-release quetiapine fumarate would have been lower. But for Defendants' ongoing, illegal anticompetitive conduct, generic versions of Seroquel XR would have become available much earlier – either through a Handa/Par and/or Accord patent victory, at-risk launch, or agreement(s) that did not include unlawful payments for delay. Plaintiff and other members of the Class would have paid lower prices for Seroquel XR and its generic equivalents. Defendants, by their conduct, have injured Plaintiff and other members of the Class by causing them to pay millions of dollars in overcharges on their purchases of extended-release quetiapine fumarate.

VII. CLASS ACTION ALLEGATIONS

137. Plaintiff brings this action on behalf of itself and, under Federal Rule of Civil Procedure 23(a) and (b)(3), as a representative of a class of End-Payor Purchasers (the "Class" or "End-Payor Purchaser Class") defined as follows:

> All persons or entities that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of brand or generic Seroquel XR from Defendants, beginning at least as early as September 29, 2011 until the effects of Defendants' conduct ceases (the "Class Period"), in the District of Columbia and Puerto Rico or any of the following states and commonwealths: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Tennessee, Utah, Vermont, West Virginia, Wisconsin, or Wyoming.

138. The following persons and entities are excluded from the above-described proposed Class:

- Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;

- All governmental entities, except for government-funded employee benefit plans;
- All persons or entities who purchased Seroquel XR for purposes of resale or directly from Defendants or their affiliates;
- Fully-insured health plans (plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligations to its members);
- Flat co-payors (consumers who paid the same co-payment amount for brand and generic drugs);
- Pharmacy benefit managers;
- All counsel of Record; and
- The Court, Court personnel and any member of their immediate families.

139. Members of the End-Payor Purchaser Class are so numerous and/or geographically dispersed that joinder is impracticable. Plaintiff believes that there are thousands of members of the Class widely dispersed throughout the United States. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many Plaintiffs to bring individual claims and join them together. The Class members are readily identifiable from information and records in Defendants' possession.

140. Plaintiff's claims are typical of members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Defendants, *i.e.*, Defendants' anticompetitive conduct deprived the Class members of the benefits of competition from less-expensive generic Seroquel XR, causing them to pay artificially inflated, *supra*-competitive prices for brand and generic Seroquel XR.

141. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

142. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and particularly class action antitrust litigation in the pharmaceutical industry.

143. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual members of the Class because Defendants have acted on grounds generally applicable to the entire class, making overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

144. Questions of law and fact common to the Class include:

- Whether defendants conspired to suppress generic competition to Seroquel XR;
- Whether Defendants' challenged conduct suppressed generic competition to Seroquel XR;
- Whether a relevant antitrust market needs to be defined in this case in light of the existence of direct proof of AstraZeneca's power to exclude generic competition and charge *supra*-competitive prices for Seroquel XR;
- If a relevant antitrust market needs to be defined, what the definition of the relevant antitrust market for analyzing AstraZeneca's monopoly power is, and whether AstraZeneca had monopoly power in the relevant antitrust market;
- Whether AstraZeneca illegally obtained or maintained monopoly power in the relevant market;
- Whether Defendants' actions were, on balance, unreasonable restraints of trade;
- Whether the activities of Defendants as alleged herein have substantially affected interstate commerce;
- Whether, and to what extent, Defendants' conduct caused antitrust injury (overcharges) to Plaintiff and the End-Payor Purchaser Class;
- The quantum of overcharge damages paid of the Class in the aggregate;
- Whether Defendants' Anticompetitive Agreements were necessary to yield some cognizable, non-pretextual procompetitive benefit;;

- Whether AstraZeneca's compensation to Handa/Par was large and unexplained;
- Whether AstraZeneca's compensation to Accord was large and unexplained; and
- Whether the Non-Compete Agreements harmed Competition;

145. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the Class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that could not be practicably pursued individually, substantially outweighs potential difficulties in management of this class action

146. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VIII. MONOPOLY POWER AND MARKET DEFINITION

147. To the extent Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, the relevant market is Seroquel XR (in all its forms and dosage strengths) and generic Seroquel XR (in all its forms and dosage strengths). The relevant geographic market is the United States.

148. AstraZeneca's anticompetitive reverse payments to Handa/Par and to Accord demonstrate that AstraZeneca enjoyed market and/or monopoly power with respect to extended- release quetiapine fumarate tablets.

149. A small but significant non-transitory price increase above the competitive level for Seroquel XR by AstraZeneca would not cause a loss of sales sufficient to make the price increase unprofitable.

150. At competitive price levels, Seroquel XR does not exhibit significant positive cross-price elasticity of demand with any product other than generic Seroquel XR.

151. AstraZeneca, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections, and high costs of entry and expansion.

152. During the relevant period, Defendants' anticompetitive conduct has significantly damaged competition and consumers through a reduction of output and higher prices caused by an elimination or reduction of lower cost generic Seroquel XR throughout the United States.

153. AstraZeneca has maintained and exercised the power to exclude and restrict competition to Seroquel XR and its AB-rated generics.

154. At all relevant times prior to November 1, 2016, AstraZeneca's market share in the relevant market was 100%, implying monopoly power.

155. At all relevant times prior to November 1, 2016, AstraZeneca had and maintained monopoly power in the market for Seroquel XR and its generic equivalents because it had the power to maintain the price of extended-release quetiapine fumarate at *supra*-competitive levels without losing sales so as to make the *supra*-competitive price unprofitable.

156. Direct proof exists that AstraZeneca had monopoly power over the price of extended-release quetiapine fumarate. Such direct evidence includes, among other things, the

abnormally-high price-cost margins enjoyed by AstraZeneca prior to entry of generic Seroquel XR and AstraZeneca's ability to profitably maintain the price of Seroquel XR well above competitive levels.

157. Manufacturers attempt to differentiate brand name drugs like Seroquel XR based on features and benefits (including safety and efficacy), not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Seroquel XR. This is due in part to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. Different patients may respond differently to different drugs and even drugs within its same therapeutic class do not constrain the price of Seroquel XR.

158. Other drugs that are not AB-rated to Seroquel XR cannot be substituted automatically for Seroquel XR by pharmacists, do not exhibit substantial cross-price elasticity of demand with Seroquel XR, and thus are not economic substitutes for, nor reasonably interchangeable with, Seroquel XR.

159. Other products are not substitutes for Seroquel XR or its generic equivalents, and the existence of other products designed to treat depression, bipolar disorder, schizophrenia, or other illnesses treated by Seroquel XR have not significantly constrained AstraZeneca's pricing of Seroquel XR. On information and belief, AstraZeneca has never lowered the price of Seroquel XR in response to the pricing of other branded or generic drugs.

160. AstraZeneca needed to control only the sales of Seroquel XR and its generic equivalents, and no other products, in order to maintain the price of Seroquel XR profitably at *supra*-competitive prices. Only the market entry of a competing, generic version of Seroquel

XR would render AstraZeneca unable to profitably maintain its prices of Seroquel XR without losing substantial sales.

IX. ANTITRUST EFFECTS

161. Defendants' anticompetitive scheme had the purpose and effect of unreasonably restraining and injuring competition by protecting Seroquel XR from generic competition. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of brand and generic Seroquel XR at *supra*-competitive prices. As a result of Defendants' illegal conduct, Plaintiff and members of the Class were compelled to pay, and did pay, artificially inflated prices for their requirements for extended-release quetiapine fumarate. Those prices were substantially greater than the prices that Plaintiff and members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of Seroquel XR was artificially inflated by Defendants' illegal conduct, and (2) Plaintiff and Class members were deprived of the opportunity to purchase lower-priced generic versions of Seroquel XR sooner, which they would have done had they had the opportunity. In addition, when generic versions of Seroquel XR were finally available, prices of generic Seroquel XR were higher than they would have been absent Defendants' unlawful conduct, and so Plaintiff and the Class have incurred overcharges on their purchases of generic Seroquel XR as well.

162. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial.

X. ANTICOMPETITIVE EFFECT ON INTERSTATE COMMERCE

163. At all material times, AstraZeneca, Par, Handa, and Accord manufactured, promoted, distributed, and/or sold substantial amounts of brand and/or generic Seroquel XR in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. During the relevant time period, in connection with the purchase and sale of brand and/or generic Seroquel XR, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

164. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants as charged in this Complaint were within the flow of, and have substantially affected, interstate commerce

XI. CONCEALMENT TOLLED THE STATUTE OF LIMITATIONS

165. Plaintiff's pre-Complaint damages claims are also timely under the doctrines of equitable tolling, the discovery rule, and fraudulent concealment.

166. Defendants, aware of their illegal scheme to monopolize the market for Seroquel XR and its injurious effects on end-payors, fraudulently concealed the scheme by failing to report it while reaping illicit profits from the *supra*-competitive prices they charged.

167. Specifically, Defendants concealed from Plaintiff the terms of the Non-Compete Agreements pursuant to which AstraZeneca agreed not to launch authorized generic Seroquel XR during Handa/Par's and Accord's 180-day exclusivity periods – a common form of "pay-for-delay." Even when limited information about the Non-Compete Agreements was made available in SEC filings or press releases, the key illegal terms, the no-AG promises,

were not disclosed. No publicly available information states that the Non-Compete Agreements precluded AstraZeneca from launching authorized generic Seroquel XR for 180 days following Handa/Par's and Accord's generic launches.

168. Moreover, the Non-Compete Agreements were inherently self-concealing. Had their unlawful provisions not been kept secret, they would not have succeeded, because of, *inter alia*, the availability of injunctive relief to prevent their performance.

169. Plaintiff remained in ignorance of this cause of action and Plaintiff's continuing ignorance was not attributable to a lack of diligence on its part.

170. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations for the Plaintiff's and the Class's claims have been tolled. Even absent fraudulent concealment, all applicable statutes of limitations are tolled by the doctrine of equitable estoppel.

171. Alternatively, if the statute of limitations is not tolled, this Complaint alleges a continuing course of conduct (including conduct within the limitations period), and Plaintiff and members of the Class can recover for damages that they suffered during the limitations period.

XII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Conspiracy and Combination in Restraint of Trade Under State Law AGAINST ALL DEFENDANTS

172. LEHB hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

173. During the Class Period, Defendants engaged in a continuing contract, combination or conspiracy with respect to the sale of Seroquel XL and/or its AB-rated generic equivalents in unreasonable restraint of trade and commerce, in violation of the various state statutes set forth below.

174. During the Class Period, Defendants entered into an unlawful reverse payment agreement that restrained competition in the market for Seroquel XR and/or its AB-rated generic equivalents.

175. Defendants' acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Seroquel XR and/or its AB-rated generic equivalents.

176. As a result of Defendants' unlawful conduct, LEHB and other similarly situated End-Payors in the Class who purchased Seroquel XR and/or its AB-rated generic equivalents have been harmed by being forced to pay artificially-inflated *supra*-competitive prices for Seroquel XR and/or its AB-rated equivalents.

177. Defendants' conspiracy had the following effects, among others:

a. It delayed generic entry of Seroquel XR in order to lengthen the period in which AstraZeneca's brand Seroquel XR could monopolize the market and make *supra*-competitive profits;

b. It kept an authorized generic off the market during Handa/Par's and Accord's 180-day generic exclusivity period, thereby allowing AstraZeneca to monopolize the generic market for Seroquel XR during the period, and allowing Handa/Par and Accord to charge s*upra*-competitive prices;

c. It raised and maintained the prices that Plaintiffs and other members of the Class would pay for Seroquel XR at *supra*-competitive levels.

178. AstraZeneca shared its monopoly power with Handa/Par and Accord, and the Defendants jointly maintained an illegal monopoly throughout that time.

179. Defendants engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Seroquel XR and/or its AB-rated generic equivalents.

180. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on End-Payors and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states, listed below. *FTC v. Actavis*, *Inc.* 570 U.S. 136 (2013).

181. By engaging in the foregoing conduct, Defendants intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of the following antitrust laws:

- Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by the Class Members;
- Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by the Class Members;
- D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by the Class Members;

- Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by the Class Members;

- 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases in Illinois by the Class Members;

- Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by the Class Members;

- Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by Class Members;

- Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by the Class Members;

- Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by the Class Members;

- Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by the Class Members;

- Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class Members;

- Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by the Class Members;

- Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by the Class Members.

- N.H. Rev. Stat. Ann. §§ 356:1, *et seq.*, with respect to purchases in New Hampshire by the Class Members;

- N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by the Class Members;

- N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by the Class Members;

- N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by the Class Members;

- N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by the Class Members;

- Or. Rev. Stat. §§ 6.46.705, *et seq.*, with respect to purchases in Oregon by the Class Members;

- S.D. Codified Laws Ann. §§ 37-1, *et seq.*, with respect to purchases in South Dakota by the Class Members;

- Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by the Class Members;

- Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by Class Members who are either citizens or residents of Utah;

- Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by the Class Members;

- W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by the Class Members; and

- Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by the Class Members.

182. Plaintiff and the Class Members have been injured in their business or property by Defendants' antitrust violations. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic versions of Seroquel XR, and (2) paying higher prices for these products than they would have paid in the absence of Defendants' wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

183. Plaintiff and the Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Defendants' anticompetitive conduct.

SECOND CLAIM FOR RELIEF

Monopolization and Monopolistic Scheme Under State Law AGAINST ALL DEFENDANTS

184. LEHB hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

185. As described above, before November 1, 2016, AstraZeneca had monopoly power in the relevant market and, after November 1, 2016, AstraZeneca shared its monopoly power with Handa/Par and Accord, and Defendants jointly maintained an illegal monopoly throughout that time.

186. Defendants willfully and unlawfully engaged in a continuing illegal conspiracy to monopolize the relevant market through at least May 1, 2017 by engaging in an anticompetitive scheme to keep AB-rated generic equivalents of Seroquel XL from the market – not as a result of providing a superior product, business acumen, or historical accident.

187. Defendants knowingly and intentionally conspired to maintain and enhance each other's monopoly power in the relevant market, injuring LEHB and the Class. Defendants accomplished this scheme by, *inter alia*,

a. delaying generic entry of Seroquel XR in order to lengthen the period in which AstraZeneca's brand Seroquel XR could monopolize the market and make *supra*-competitive profits;

b. keeping an authorized generic off the market during Handa/Par's and Accord's 180-day generic exclusivity period, thereby allowing Handa/Par and Accord to monopolize the generic market for Seroquel XR during the period, and allowing Handa/Par and Accord to charge *supra*-competitive profits;

c. Raising and maintaining the prices so that Plaintiff and other members of the Class would pay for Seroquel XR at *supra*-competitive levels.

188. The goal, purpose, and effect of Defendants' scheme was also to maintain and extend AstraZeneca's monopoly power with respect to Seroquel XR. Defendants' illegal scheme allowed AstraZeneca to continue charging *supra*-competitive prices for Seroquel XR,

without a substantial loss of sales, reaping substantial unlawful monopoly profits. Defendants' scheme also allowed Handa/Par and Accord to reap the benefits of reduced generic competition in the United States.

189. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on End-Payors and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose.

190. As a result of Defendants' illegal conduct, Plaintiff and members of the Class were compelled to pay, and did pay, more than they would have paid for Seroquel XR and/or its generic equivalent absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun selling generic Seroquel XR sooner than they did, and prices for Seroquel XR and generic Seroquel XR would have been lower, sooner.

191. Had manufactures of generic Seroquel XR entered the market and lawfully competed with Defendants in a timely fashion, Plaintiff and other members of the Class would have substituted lower-priced generic Seroquel for the higher-priced brand-name Seroquel for some or all of their Seroquel requirements, and/or would have paid lower net prices on their remaining Seroquel XR and generic Seroquel XR purchases.

192. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of Seroquel XR well before November 1, 2016, and they would have been able to market such versions more successfully.

193. By engaging in the foregoing conduct, Defendants intentionally and wrongfully engaged in a monopolistic scheme in violation of the following antitrust laws:

- Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by the Class Members;

● Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by the Class Members;

● D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by the Class Members;

● Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by the Class Members;

● 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases in Illinois by the Class Members;

● Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by the Class Members;

● Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by Class Members;

● Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by the Class Members;

● Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by the Class Members;

● Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by the Class Members;

● Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class Members;

● Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by the Class Members;

● Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by the Class Members.

● N.H. Rev. Stat. Ann. §§ 356:1, *et seq.*, with respect to purchases in New Hampshire by the Class Members;

● N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by the Class Members;

● N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by the Class Members;

● N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by the Class Members;

- N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by the Class Members;

- Or. Rev. Stat. §§ 6.46.705, *et seq.*, with respect to purchases in Oregon by the Class Members;

- S.D. Codified Laws Ann. §§ 37-1, *et seq.*, with respect to purchases in South Dakota by the Class Members;

- Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by the Class Members;

- Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by Class Members who are either citizens or residents of Utah;

- Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by the Class Members;

- W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by the Class Members; and

- Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by the Class Members.

194. Plaintiff and the Class Members have been injured in their business or property by Defendants' antitrust violations. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic versions of Seroquel XR, and (2) paying higher prices for these products than they would have paid in the absence of Defendants' wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

195. Plaintiff and the Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Defendants' anticompetitive conduct.

THIRD CLAIM FOR RELIEF

Violation of State Consumer Protection Statutes
(AGAINST ALL DEFENDANTS)

196. LEHB hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

197. Defendants engaged in unfair methods of competition, and unfair, unconscionable, and/or deceptive acts or practices to wrongfully perpetuate their concerted conduct to restrain trade in the relevant market.

198. As a direct and proximate result of Defendants' unfair, unconscionable, and/or deceptive conduct, Plaintiff and the Class members were: (1) denied the opportunity to purchase lower-priced generic Seroquel XR; and (2) paid higher prices for Seroquel XR and/or generic Seroquel XR than they would have paid but for Defendants' unlawful conduct.

199. Also, as a direct and proximate result of Defendants' unfair, unconscionable, and deceptive conduct, AstraZeneca refrained from selling a competing authorized generic when Handa/Par and Accord began selling generic Seroquel XR, which forced Plaintiff and the Class members to pay more for generic Seroquel than they would have absent Defendants' unfair and oppressive acts.

200. The gravity of harm from Defendants' wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiff and the Class members could not reasonably have avoided injury from Defendants' wrongful conduct.

201. There was a gross disparity between the price that Plaintiff and the Class members paid for Seroquel XR and the value they received. Much more affordable generic Seroquel XR would have been available sooner and in greater quantity, and prices for

Seroquel XR would have been far lower, but for Defendants' unfair, unconscionable, and deceptive conduct.

202. As a direct and proximate result of Defendants' anticompetitive, unfair, unconscionable, and/or deceptive conduct, Plaintiff and the Class members were denied the opportunity to purchase generic Seroquel XR and forced to pay higher prices for Seroquel XR and generic Seroquel XR.

203. By engaging in such conduct, Defendants violated the following consumer protection laws:

- Ariz. Code §§ 44-1521, et seq., with respect to purchases of Seroquel XR and AB-rated generic equivalents in Arizona by End-Payor Class members.
- Ark. Code §§ 4-88-101, et seq., with respect to purchases of Seroquel XR and AB-rated generic equivalents in Arkansas by End-Payor Class members.
- Cal. Bus. & Prof Code §§ 17200, et seq., with respect to purchases of Seroquel XR and AB-rated generic equivalents in California by End-Payor Class members.
- D.C. Code §§ 28-3901, et seq., with respect to purchases of Seroquel XR and AB-rated generic equivalents in D.C. by End-Payor Class members.
- Fla. Stat. §§ 501.201, et seq., with respect to purchases of Seroquel XR and AB-rated generic equivalents in Florida by End-Payor Class Members.
- Haw. Rev. Stat. §§ 481-1 to 481-11 with respect to purchases of Seroquel XR and AB-rated generic equivalents in Hawaii by End-Payor Class members.
- Idaho Code §§ 48-601, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in Idaho by End-Payor Class members.

● 815 ILCS §§ 505/1, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in Illinois by End-Payor Class.

● Kan. Stat. §§ 50-623, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in Kansas by End-Payor Class members.

● 5 Me. Rev. Stat. §§ 207, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in Maine by End-Payor Class members.

● Mass. Ann. Laws, ch. 93A, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in Massachusetts by End-Payor Class members.

● Mich. Stat. §§ 445.901, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in Michigan by End-Payor Class members.

● Minn. Stat. §§ 325F.68, *et seq.*, and Minn. Stat. § 8.31, et seq., with respect to purchases of Seroquel XR and AB-rated generic equivalents in Minnesota by End-Payor Class members.

● Mo. Stat. §§ 407.010, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in Missouri by End-Payor Class members.

● Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in Nebraska by End-Payor Class members.

● Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in Nevada by End-Payor Class members.

● N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in New Hampshire by End-Payor Class members.

● N.M. Stat. §§ 57-12-1, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in New Mexico by End-Payor Class members.

● N.Y. G.B.L. §§ 349, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in New York by End-Payor Class members.

● N.C. Gen. Stat. §§ 75-1.2, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in North Carolina by End-Payor Class members.

● Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in Oregon by End-Payor Class members.

● R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in Rhode Island by End-Payor Class members.

● S.D. Codified Laws § 37-24-6, with respect to purchases of Seroquel XR and AB-rated generic equivalents in South Dakota by End-Payor Class members.

● Tenn. Code §§ 47-18-101, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in Tennessee by End-Payor Class members.

● Utah Code §§ 13-11-1, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in Utah by End-Payor Class members.

● Va. Code §§ 59.1-196, *et seq.* with respect to purchases of Seroquel XR and AB-rated generic equivalents in Virginia by End-Payor Class members.

● Vt. Stat Ann. 9, § 2453, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in Vermont by End-Payor Class members.

● W. Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases of Seroquel XR and AB-rated generic equivalents in West Virginia by End-Payor Class members .

204. Plaintiff and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair, unconscionable, and/or deceptive conduct. Their injury consists of paying higher prices for Seroquel XR and/or generic

Seroquel XR than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

205. On behalf of itself and the Class, Plaintiff seeks all appropriate relief provided for under the foregoing statutes.

FOURTH CLAIM FOR RELIEF
Unjust Enrichment
(AGAINST ALL DEFENDANTS)

206. LEHB hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

207. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

208. Defendants have financially benefited from overcharges on sales of branded and generic versions of Seroquel XR, which resulted from the unlawful acts alleged in this Complaint. These overcharges were borne by Plaintiff and the Class Members who purchased and/or reimbursed all or part of the purchase price of branded and generic Seroquel XR. The benefits conferred upon Defendants are substantial and measurable, in that the revenues Defendants have earned due to unlawful overcharges are ascertainable by review of both sales records and the unlawful pay-for-delay agreement itself.

209. Moreover, AstraZeneca's promise not to launch a competing authorized generic version of Seroquel XR during Handa/Par's and Accord's 180-day marketing exclusivity period was inextricably linked to the overcharges that Plaintiff and the Class Members were forced to pay and thus part of the enrichment of Defendants at the expense of Plaintiff and the Class Members.

210. For years, there was gross disparity between the price that Plaintiff and the Class Members paid for Seroquel XR compared to what they would have paid for less expensive generic versions of Seroquel XR, which should and would have been available but for Defendants' unlawful and inequitable conduct.

211. Defendants repeatedly and continuously received financial benefits at the expense of Plaintiff and the Class Members through each sale of branded and generic versions of Seroquel XR at an inflated price.

212. It would be futile for Plaintiff and the Class Members to seek a remedy from any party with whom they had or have privity of contract. Defendants have paid no consideration to any other person for any of the benefits they received indirectly from Plaintiff and the Class Members.

213. It would be futile for Plaintiff and the Class Members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Seroquel XR, as those intermediaries cannot reasonably be expected to compensate Plaintiff and the Class Members for Defendants' unlawful conduct.

214. The financial benefits that Defendants derived rightfully belong to Plaintiff and the Class Members, which paid anticompetitive prices that inured to Defendants' benefit.

215. It would be inequitable under the unjust enrichment principles of the states listed below for Defendants to retain any of the overcharges that Plaintiff and the Class Members paid for branded and generic versions of Seroquel XR which were derived from Defendants' anticompetitive, unfair, and unconscionable methods, acts, and trade practices.

216. Defendants should be compelled to disgorge all unlawful or inequitable proceeds received by them into a common fund for the benefit of Plaintiff and the Class Members.

217. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received, which arise from overpayments for branded and generic versions of Seroquel XR by Plaintiff and the Class Members.

218. Plaintiffs and the Class Members have no adequate remedy at law.

219. By engaging in the foregoing unlawful or inequitable conduct, which deprived Plaintiff and the Class Members of the opportunity to purchase lower-priced generic versions of Seroquel XR and forced them to pay higher prices for branded and generic versions of Seroquel XR, Defendants have been unjustly enriched in violation of the common law of various states and commonwealths, as outlined below:

Alabama

220. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Alabama at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Class as a direct result of the unlawful overcharges and have retained this money. Defendants have benefitted at the expense of the Class from revenue resulting from unlawful overcharges for Seroquel XR or its AB-rated generic equivalents. It is inequitable for Defendants to accept and retain the benefits received without compensating the Class.

Alaska

221. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Alaska at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefits bestowed upon them by the Class. Defendants accepted and retained the benefits bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Arizona

222. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Arizona at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Seroquel XR or its AB-rated generic equivalents. The Class has been impoverished by the overcharges for Seroquel XR or its AB-rated generic equivalents resulting from Defendants' unlawful conduct. Defendants' enrichment and the Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment and the Class's impoverishment, because the Class paid *supra*-competitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Class has no remedy at law.

Arkansas

223. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Arkansas at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Class as a direct result of the unlawful overcharges and have retained this money. Defendants have paid no consideration to any other person in exchange for this money. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

California

224. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in California at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class as a direct result of the unlawful overcharges. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of the Class.

Colorado

225. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Colorado at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants have benefitted at the expense of the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Connecticut

226. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Connecticut at prices that were more than they would have been but for Defendants' actions. Defendants were benefitted in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants have paid no consideration to any other person in exchange for this benefit. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of the Class.

Delaware

227. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Delaware at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Seroquel XR or its AB-rated generic equivalents. The Class has been impoverished by the overcharges for Seroquel XR or its AB-rated generic equivalents resulting from Defendants' unlawful conduct. Defendants' enrichment and the Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment, because the Class paid *supra*-competitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Class has no remedy at law.

District of Columbia

228. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in the District of Columbia at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful

overcharges to the economic detriment of the Class. Defendants retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits.

Florida

229. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Florida at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefits bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Georgia

230. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Georgia at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Hawaii

231. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Hawaii at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges

to the economic detriment of the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Idaho

232. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Idaho at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit conferred upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Illinois

233. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Illinois at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Class. It is against equity, justice, and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Iowa

234. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Iowa at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Seroquel XR or its AB-rated generic

equivalents, which revenue resulted from anticompetitive prices paid by d the Class, which inured to Defendants' benefit. Defendants' enrichment has occurred at the expense of the Class. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Class.

Kansas

235. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Kansas at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Kentucky

236. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Kentucky at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit conferred upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Louisiana

237. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Louisiana at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Seroquel XR or its AB-rated generic equivalents. The Class has been impoverished by the overcharges for Seroquel XR or its AB-rated generic equivalents resulting from Defendants' unlawful conduct. Defendants' enrichment and the Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment, because the Class paid *supra*-competitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Class has no other remedy at law.

Maine

238. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Maine at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Maryland

239. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Maryland at prices that were more than they would have been but for Defendants' actions. The Class has conferred an

economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Massachusetts

240. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Massachusetts at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit conferred upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Michigan

241. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Michigan at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Minnesota

242. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Minnesota at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated and knowingly accepted the benefits bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Mississippi

243. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Mississippi at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Class as a direct result of the unlawful overcharges. Defendants retain the benefit of overcharges received on the sales of Seroquel XR or its AB-rated generic equivalents, which in equity and good conscience belong to the Class on account of Defendants' anticompetitive conduct. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Missouri

244. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Missouri at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit bestowed upon them

by the Class. Defendants accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Class.

Montana

245. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Montana at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Nebraska

246. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Nebraska at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Class as a direct result of the unlawful overcharges and have retained this money. Defendants have paid no consideration to any other person in exchange for this money. In justice and fairness, Defendants should disgorge such money and remit the overcharged payments back to the Class.

Nevada

247. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Nevada at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges for Seroquel XR or its AB-rated generic equivalents. Defendants appreciated the benefits bestowed upon them by the Class, for which they have paid no consideration to any other person.

Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

New Hampshire

248. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in New Hampshire at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Under the circumstances, it would be unconscionable for Defendants to retain such benefits.

New Jersey

249. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in New Jersey at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the Class. Defendants have paid no consideration to any other person for any of the unlawful benefits they received from the Class with respect to Defendants' sales of Seroquel XR or its AB-rated generic equivalents. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Class.

New Mexico

250. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in New Mexico at prices that were more than they would have been but for Defendants' actions. Defendants have knowingly benefitted at the expense of the Class from revenue resulting from unlawful overcharges for Seroquel XR or its AB-rated generic equivalents. To allow Defendants to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to Defendants' benefit and because Defendants have paid no consideration to any other person for any of the benefits they received.

New York

251. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in New York at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Seroquel XR or its AB-rated generic equivalents, which revenue resulted from anticompetitive prices paid by the Class, which inured to Defendants' benefit. Defendants' enrichment has occurred at the expense of the Class. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

North Carolina

252. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in North Carolina at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The Class did not interfere with Defendants'

affairs in any manner that conferred these benefits upon Defendants. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the Class. The benefits conferred upon Defendants are measurable, in that the revenue Defendants have earned due to unlawful overcharges are ascertainable by review of sales records. Defendants consciously accepted the benefits conferred upon them.

North Dakota

253. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in North Dakota at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Seroquel XR or its AB-rated generic equivalents. The Class has been impoverished by the overcharges for Seroquel XR or its AB-rated generic equivalents resulting from Defendants' unlawful conduct. Defendants' enrichment and the Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment, because the Class paid *supra*-competitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Class has no remedy at law. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Class.

Oklahoma

254. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Oklahoma at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Class as a direct result of the unlawful overcharges and have retained this money.

Defendants have paid no consideration to any other person in exchange for this money. The Class has no remedy at law. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Oregon

255. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Oregon at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of the benefit bestowed upon them by the Class. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Class.

Pennsylvania

256. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Pennsylvania at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Puerto Rico

257. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Puerto Rico at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Seroquel XR or its AB-rated

generic equivalents. The Class has been impoverished by the overcharges for Seroquel XR or its AB-rated generic equivalents resulting from Defendants' unlawful conduct. Defendants' enrichment and the Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment and the Class's impoverishment, because the Class paid *supra*-competitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Class has no remedy at law.

Rhode Island

258. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Rhode Island at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

South Carolina

259. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in South Carolina at prices that were more than they would have been but for Defendants' actions. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the Class. Defendants realized value from the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

South Dakota

260. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in South Dakota at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants were aware of the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits without reimbursing the Class.

Tennessee

261. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Tennessee at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class. It would be futile for the Class to seek a remedy from any party with whom they have privity of contract. Defendants have paid no consideration to any other person for any of the unlawful benefits they received indirectly from the Class with respect to Defendants' sales of Seroquel XR or its AB-rated generic equivalents. It would be futile for The Class to exhaust all remedies against the entities with which the Class has privity of contract because the Class did not purchase Seroquel XR or its AB-rated generic equivalents directly from any Defendant.

Texas

262. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Texas at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants were aware of or appreciated the benefit bestowed upon them by the Class. The circumstances under which Defendants have retained the benefits bestowed upon them by the Class are inequitable in that they result from Defendants' unlawful overcharges for Seroquel XR or its AB-rated generic equivalents. The Class has no remedy at law.

Utah

263. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Utah at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Vermont

264. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Vermont at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants accepted the benefit bestowed upon them by

the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Virginia

265. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Virginia at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of the benefit bestowed upon them. Defendants should reasonably have expected to repay the Class. The benefits conferred upon Defendants were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from Defendants' illegal and unfair actions to inflate the prices of Seroquel XR or its AB-rated generic equivalents. Defendants have paid no consideration to any other person for any of the benefits they have received from the Class.

Washington

266. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Washington at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit conferred upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

West Virginia

267. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in West Virginia at prices

that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Wisconsin

268. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Wisconsin at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Wyoming

269. Defendants unlawfully overcharged Class Members, who made purchases of or reimbursements for Seroquel XR or its AB-rated generic equivalents in Wyoming at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants accepted, used and enjoyed the benefits bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

XIII. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: September 5, 2019

Respectfully submitted,

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